Missouri Pharmacy Practice Guide

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Missouri Board of Pharmacy

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MESSAGE FROM THE BOARD

The Missouri Board of Pharmacy is pleased to provide the *Missouri Pharmacy Practice Guide*. The *Pharmacy Practice Guide* is designed to increase licensee compliance by providing guidance on basic provisions of Missouri's law governing pharmacy practice.

Since 1909, the Board has served Missouri citizens through the regulation and licensing of the pharmacy profession. The Board is an autonomous Board within the Division of Professional Registration, an agency of the Missouri Department of Insurance, Financial Institutions and Professional Registration. The Board consists of seven (7) members, including, one (1) public member and six (6) licensed pharmacists actively engaged in the practice of pharmacy in Missouri.

The Board's mission is to serve and protect the public in the practice of pharmacy by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetency, misconduct, gross negligence, fraud, misrepresentation and dishonesty;
- Licenses only qualified professionals by examination and evaluation of competency; and
- Enforces practice standards by implementing legislation and adopting administrative rules.

Additional pharmacy resources and compliance materials are available on the Board's website at http://pr.mo.gov/pharmacists. The Board also provides license and regulatory updates via e-alerts and the Board's electronic newsletter. Interested parties can sign up for the Board's newsletter and e-alerts at http://pr.mo.gov/pharmacists-newsletter.asp.

The Missouri Pharmacy Practice Guide is provided for informational purposes only. The Practice Guide does not constitute a comprehensive review of all governing law or controlled substance requirements. To ensure compliance, licensees should thoroughly review Chapter 338, RSMo, 20 CSR 2220 and all applicable state and federal laws. The Practice Guide does not constitute a rule statement of general applicability or binding law. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The Board expressly reserves the right to revise the contents as deemed appropriate or necessary. Questions regarding this document may be addressed to the Board office.

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A.1 GENERAL AUTHORITY

Pursuant to Chapter 338, of the Revised Statutes of Missouri, the Board has regulatory authority over the practice of pharmacy in Missouri. The Board's duties include, but are not limited to, monitoring compliance, investigating complaints, inspecting pharmacies/drug distributors and licensing pharmacists, intern pharmacists, pharmacy technicians, pharmacies and drug distributors. The Board's administrative rules are promulgated in Chapter 20 CSR 2220 of the Missouri Code of State Regulations.

The Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") regulates controlled substance distribution in Missouri. However, the Board monitors and inspects compliance with applicable controlled substance drug laws. For controlled substance questions, contact BNDD at (573) 751-6321 or e-mail bndd@health.mo.gov. E-mail is preferred.

A.2 COMPLIANCE AND EDUCATION

The Board is committed to promoting voluntary compliance through education and awareness. A variety of free practice resources and compliance guides are available on the Board's website. The Board also hosts periodic webinars to discuss emerging compliance issues and trends. Licensees should sign-up for the Board's newsletter and e-alerts at http://pr.mo.gov/pharmacists-newsletter.asp to receive webinar notices and other regulatory updates, including, notification of technician disciplinary actions.

A.3 DISCIPLINARY AUTHORITY

The Board may impose discipline if a licensee/registrant has, or if any officer, owner, pharmacist-in-charge or manager-in-charge has, committed any act identified in § 338.055.2. Grounds for disciplinary action include, but are not limited to:

1. Using any controlled substance or alcoholic beverage to an extent that such use impairs a licensee's/registrant's ability to practice;
2. Being finally adjudicated and found guilty, or entering a plea of guilty or nolo contendere, for any criminal offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated by Chapter 338, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude (this includes a suspended imposition of sentence or "SIS");
3. Obtaining or attempting to obtain any fee or other compensation by fraud, deception or misrepresentation;
4. Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by Chapter 338;
5. Violating, or assisting or enabling any person to violate, Chapter 338 or any Board rule;
6. Assisting or enabling any person to practice or offer to practice without the required Board license, registration or permit;
7. Violating any professional trust or confidence;
8. Using false, misleading or deceptive advertising;
9. Violating any state or federal drug law or regulation;
10. Intentionally substituting or changing the content, formula or brand of any drug prescribed without prior prescriber approval; or
11. Using any controlled substance unless it is prescribed, dispensed, or administered by an authorized health care provider. *See § 338.055 for a list of all disciplinary grounds.*

Disciplinary action may include, but is not limited to, public censure, probation, suspension or revocation. If revoked, the Board may prohibit a licensee from reapplying for licensure for up to seven (7) years.

A.4 MANDATORY REPORTING OF DISCIPLINE/ADVERSE ACTIONS

Section 338.075, RSMo, requires all Board licensees, registrants and permit holders to report to the Board:

- Any final adverse action taken by another licensing state, jurisdiction or governmental agency against any license to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug distributor, drug manufacturer or drug outsourcing facility;
- Any surrender of a license or authorization to practice as a pharmacist, pharmacy, drug distributor, technician, intern pharmacist or drug outsourcer; and
- Any exclusion to participate in any state or federal funded health care program for fraud or abuse or for submitting any false/fraudulent claim for payment or reimbursement (e.g., Medicare, Medicaid or MoHealthNet).

An electronic reporting form is available on the Board's website. Pending final rulemaking, licensees should report adverse actions/exclusions to the Board within seven (7) days. *[See C.17 for additional mandatory reporting requirements (pharmacists) and L.4 (technicians)].*

B.1 GENERAL REQUIREMENTS

No person may perform, or offer to perform, the "practice of pharmacy" in the state of Missouri without a current and active Missouri pharmacist license. Section 338.010.1, RSMo, defines "the practice of pharmacy" as:

- Interpreting, implementing, and evaluating medical prescription orders, including, handling or facilitating the dispensing of such orders;
- Providing medication therapy services, as defined by rules of the Board;
- Compounding, dispensing and labeling drugs/devices pursuant to a medical prescription order;
- Administering vaccines by protocol or administering medication by prescription drug order;
- Participating in drug selection and drug utilization reviews according to state law;
- Consulting with patients and other health care practitioners about the safe and effective use of drugs and devices; and,
- Offering or performing any act or service necessary in the conduct, operation, management and control of a pharmacy. [§ 338.010]

Pharmacist licensure is not required for legally registered practitioners of medicine, dentistry, podiatry, veterinary medicine or optometry that are lawfully compounding or dispensing their own prescriptions. [§ 338.010.1]

In addition to a Missouri pharmacist license, additional certification and/or notification is required for pharmacists performing the following services:

- Immunizing by Protocol (See Section I)
- Administering Medication By Prescription Order (See Section J)
- Medication Therapy Services (See Section K)

Missouri law is silent on pharmacists independently performing labtoratory testing. Absent statutory direction, licensees should consult with legal counsel for additional guidance. The Board cannot provide legal advice.

B.2 RENEWALS/CONTINUING EDUCATION

Pharmacist licenses are renewed biennially in even numbered years (i.e., 2016, 2018). To renew, pharmacists must file a renewal application with the required fee and complete 30 hours of approved continuing education (CE). [20 CSR 2220-7.080]. One continuing education unit (CEU) is the equivalent of ten clock hours of CE.

CE must have been earned from November 1st of the prior renewal year and October 31st of the current renewal year. For example, licensees renewing in 2018 must have completed 30 CE hours from November 1, 2016 to October 31, 2018. Although the CE deadline is October 31st, CE must be completed before a renewal is submitted. All CE must be provided by an ACPE accredited provider or approved by the Board in advance. Only non-ACPE courses have to be pre-approved. The Board will not approve non-ACPE classes that have already been taken.

Licensees should review 20 CSR 2220-7.080 for a complete listing of Missouri CE requirements. Additional CE information is provided in the Pharmacist CE Guide (Appendix A). Proof of CE must be maintained in the licensee's records for two renewal cycles and provided on request. The Board randomly audits CE compliance.

B.3 CHANGE OF ADDRESS/EMPLOYMENT

Pharmacists and pharmacy technicians are required to notify the Board of employment changes no later than fifteen (15) days after the change. [20 CSR 2220-2.010(1)(Q), 20 CSR 2220-2.700(3)]. Address and employment changes may be submitted online at https://renew.pr.mo.gov/pharmacists-coa.asp.

To ensure sufficient communication, pharmacists, pharmacy technicians and interns should immediately notify the Board of address changes. 20 CSR 2220-2.010(1)(N); 20 CSR 2220-2.700(2). Correspondence returned to the Board because of an incorrect address will not be resent until a correct address is provided.

B.4 JURY DUTY

Section 494.430.1(4), RSMo, allows a pharmacist to be excused from jury duty if he/she is providing health care services to patients and service as a juror would be detrimental to patient health. This exemption is not automatic and must be granted by a judge.

B.5 MILITARY LICENSEES

A Missouri pharmacist license is not required for legally qualified pharmacists serving in the United States armed forces, or pharmacists employed by the U.S. government or any U.S. agency/bureau, who are engaged in the practice of pharmacy while in the discharge of their official duties. This exemption only applies to pharmacy services provided as part of the pharmacist's federal/military duties or employment. A Missouri pharmacy license would be required if the pharmacist is practicing outside of his/her federal or military duties (i.e., independently practicing at a retail pharmacy). [§ 338.020.2, RSMo.]

Renewals: Section § 338.060.2, RSMo, provides a pharmacist may renew his/her license for no fee if the pharmacist's license expired while on active duty in the U.S. armed services, Coast Guard or the state militia, or expired while in training or education prior to being inducted into the military. Renewal applications must be submitted within one (1) year after terminating the applicable military service, training or education. Similarly, § 41.946, RSMo, waives Missouri's CE requirements for licensees who expire while completing military service.

To submit a late renewal or to request a CE exemption, pharmacists must furnish the Board with an affidavit attesting that the pharmacist was engaged in military service as provided by § 338.060.2, RSMo. Alternatively, the Board will accept official discharge documentation. The affidavit/documentation must include the pharmacist's name, the date service/training/education began, and ended and the status of termination (i.e., completed, honorably discharged, etc.). For questions about military renewals/licensing, call (573) 751-0092 or e-mail pharmacist@pr.mo.gov. *Note: The late renewal allowance does not apply if dishonorably discharged.*

C.1 PHARMACY LICENSURE

No person or entity may open, establish, operate or maintain a pharmacy in the state of Missouri without a valid Missouri pharmacy permit. A pharmacy includes, but is not limited to, any place:

- Where the practice of pharmacy is offered or conducted or where the practice of pharmacy is provided by a pharmacist or someone acting under the pharmacist's supervision or authority.
- Where drugs, chemicals, medicines, prescriptions, or poisons are compounded, prepared, dispensed, sold or offered for sale at retail;
- Where the words "pharmacist", "apothecary", "pharmacy", "drugstore", "drugs" and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services; or
- Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons. [§ 338.210; 338.260]

C.2 PHARMACY CLASSIFICATIONS

The Board issues the following classes of pharmacy permits [§ 338.220, 20 CSR 2220-2.020(9)]:

CLASS	DESCRIPTION
Class A (Community/ Ambulatory)	Required to provide pharmacy services to the general public (i.e., retail).
Class B (Hospital Pharmacy)	A pharmacy owned, managed, or operated by a hospital as defined by § 197.020 or a hospital clinic or facility under common control, management or ownership of the same hospital or hospital system. [§ 338.220.6]. ** Licensure is not required for hospital pharmacies operating under the jurisdiction of the Missouri Department of Health and Senior Services. See section C.18 for additional information.*
Class C (Long-Term Care)	Required for pharmacies dispensing drugs/devices to patients residing in a long-term care facility which would include a nursing home, retirement facility, mental care facility or any other facility that provides extended health care to resident patients. *See also Section M.*
Class D (Non-Sterile Compounding)	Required for pharmacies providing non-sterile compounding as defined by 20 CSR 2220-2.400(3), in batch quantities using bulk active ingredients. [See 20 CSR 2220-2.400].
Class E (Radiopharmaceutical)	Required for pharmacies preparing/dispensing radioactive drugs as defined by the Food and Drug Administration (FDA) to health care providers for treatment/ diagnosis. Class-E pharmacies must maintain a qualified nuclear pharmacist. The nuclear pharmacist must be personally present and directly supervise all personnel assisting in drug preparation/dispensing. [See 20 CSR 2220-2.500].

CLASS	DESCRIPTION
Class F (Renal Dialysis)	Required for pharmacies dispensing renal dialysis solutions and other drugs/ devices associated with dialysis care. Renal dialysis pharmacies may not be open to the general public and may only dispense renal dialysis solutions and renal dialysis associated drugs, supplies or devices. [See 20 CSR 2220-2.600].
Class G (Medical Gas)	Required for pharmacies providing oxygen and other prescription gases by prescription for therapeutic use.
Class H (Sterile Product Compounding)	Required for sterile compounding pharmacies, as defined by 20 CSR 2220-2.200.
Class I (Consultant)	Required for any location where the practice of pharmacy is conducted but which is not being used for the procurement, storage, possession or ownership of drugs.
Class J (Shared Service)	Required for pharmacies engaged in shared serves with/for another pharmacy such as, filling/refilling medication, central fill services, drug utilization review or therapeutic interventions. See Section C.19. [20 CSR 2220-2.650].
Class K (Internet)	Required for pharmacies receiving, reviewing, preparing, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for new prescriptions originated from the internet for more than 90% of the pharmacy's total new prescription volume on any day. *See the Ryan Haight Act for additional federal requirements* .
Class L (Veterinary)	Required for entities selling, dispensing, or filling a prescription only legend drug for animal use. *Note: Class A pharmacies may dispense medication for animal use without an additional Class L permit. See 20 CSR 2220-2.675 for Class L Veterinary requirements.*
Class M: Specialty (Bleeding Disorder)	Required for pharmacies providing blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders. See 20 CSR 2220-6.100. See New Missouri Standards for Pharmacies Dispensing Blood-Clotting Therapies for additional guidance.
Class N: Automated Dispensing System (Health Care Facility)	Required for pharmacies operating automated/mechanical systems in a health care facility to store, package or dispense medication. See 20 CSR 2220-2.900.**
Class O: Automated Dispensing System (Ambulatory)	Required for pharmacies operating automated/mechanical systems in a ambulatory setting to store, package or dispense medication. See 20 CSR 2220-2.900.**
Class P: Practitioner Office/ Clinic	Required for pharmacies operating in a practitioner's office/clinic. A pharmacy permit is not required for practitioner office dispensing to their own patients.**

***Final Board rules have not been promulgated.*

Pharmacies may only engage in the pharmacy activities allowed for the class(es) reflected on the pharmacy's permit. To add or delete a class, a Change of Classification Application must be filed. Pharmacies may not function under an added class until the Board has issued a new permit reflecting the new classification.

Pharmacies must comply with all regulations pertaining to any class listed on the pharmacy's permit even if they are not actually performing the activities. For example, a Class H Sterile Product pharmacy must comply with the Board's sterile compounding rules even if the pharmacy isn't currently compounding.

C.3 GENERAL REQUIREMENTS

Applicants for a pharmacy permit must file an application with the Board and pay the applicable fee. Applicants must meet the following requirements [20 CSR 2220-2.010(1)(C) – (F), 20 CSR 2220-2.020]:

- The pharmacy must designate and be under the supervision of a "pharmacist-in-charge";
- Equipment and facilities must be operated in a manner that will not endanger the public health or safety;
- The pharmacy must be equipped with proper pharmaceutical and sanitation appliances;
- The pharmacy must be maintained in a clean, sanitary and orderly manner. Animals are not allowed in the pharmacy, except for service animals as defined by the American with Disabilities Act [20 CSR 2220-2.010(F)]; and
- Proposed/current operations must comply with Chapter 338 and all applicable state/federal law.

Pharmacies may be owned by unlicensed persons/entities. However, the practice of pharmacy may only be conducted by licensed pharmacists.

In-state pharmacies must pass a Board inspection prior to licensure. Non-resident pharmacies must have an active pharmacy license in the applicant's home state. The Board may inspect a non-resident pharmacy if deemed necessary.

C.4 EQUIPMENT/REFRIGERATION

Pharmacies must be equipped with proper equipment and reference manuals for the pharmacy services provided. . [20 CSR 2220-2.010(1)(C) – (D)]. The Board does not approve specific brands or products.However, the following minimum equipment is required:

- Any basic equipment recognized by the latest edition of the *United States Pharmacopeia (USP)*, the *United States Pharmacopeia/Drug Information (USP/DI)* or *Remington's: The Science and Practice of Pharmac*y;
- A suitable machine/device for numbering prescriptions or assigning a unique identifier;
- Printing equipment for prescription labels;
- The current or latest edition of a reference manual(s) which includes all FDA approved drugs and information on pharmacology, dosages and clinical effects of drugs, and patient information; and
- A current edition of statutes and rules governing the pharmacy's practice.

Reference materials can be maintained electronically or in print. However, the materials must be accessible to pharmacy staff and immediately retrievable during an inspection.

Drug Storage Areas: Pharmacies must have adequate refrigeration and sufficient storage space for drug inventory. Drug

storage areas must be thermostatically controlled within the temperature requirement(s) provided by the manufacturer or the latest edition of USP. [20 CSR 2220-2.010(1)(G)]. To ensure compliance, drug storage areas should have a thermometer or other temperature device to monitor temperatures. Food and beverage items that are not in their original, sealed manufacturer packaging must be stored separately from drugs and drug-related devices. Opened food or beverage items intended for patient use with medication or used in compounding may be stored in the same area as drugs and drug-related devices as long as the items are separated from other inventory and sanitary conditions are maintained at all times. [20 CSR 2220-2.010(1)(G)].

Licensees should review package labeling as some products have special storage and temperature requirements and may not be stored in certain refrigeration/freezer units (i.e., dormitory style refrigerators).

C.5 PHARMACIST-IN-CHARGE

Each licensed pharmacy must designate a licensed pharmacist to serve as "pharmacist-in-charge" (PIC). [20 CSR 2220-2.010(1)(M)]. Along with the permitholder, the PIC is personally responsible for supervising pharmacy activities and for ensuring full compliance with all state and federal drug laws.

Rule 20 CSR 2220-2.090 contains a detailed listing of PIC responsibilities/duties. Pharmacists should carefully review the rule prior to assuming accepting responsibilities. The Board also recommends that pharmacists review:

- The nature and volume of the pharmacy's activities, and
- The pharmacy's prior compliance history. This should include reviewing the Board's previous inspection reports/ compliance notices and any prior disciplinary orders. New PICs should make sure previous violations have been addressed and corrected.

A pharmacist may serve as PIC for more than one pharmacy. However, the PIC must be actively engaged in the operation of each pharmacy and may be held responsible for compliance violations even when the PIC is not present.

Pharmacists must immediately notify the Board if he/she stops serving as PIC. [20 CSR 2220-2.010(1)(M)]. The pharmacy may not continue operations until a new PIC has been designated. Once designated, the new PIC may begin serving immediately. However, the permit holder must promptly submit a fully completed Pharmacist-In-Charge Change Application to officially complete the change. [20 CSR 2220-2.010(1)(M)]. Applications not received in a timely fashion may result in the PIC designation being voided or other disciplinary review/action. The mailing date should be documented and maintained in the pharmacy's records.

Both the permit holder and PIC are responsible for completing a controlled substance inventory at the time of a PIC change. [20 CSR 2220-2.090(2)(T)]. The inventory must include all Schedule II through V controlled substances, including, Schedule V pseudoephedrine containing over-the-counter products. Documentation of the inventory must be maintained in the pharmacy's records. To ensure accuracy, the Board recommends that the former and new PIC jointly conduct the inventory.

Agreeing to serve as PIC is a serious responsibility. Once again, **PICS CAN BE HELD PERSONALLY RESPONSIBLE FOR COMPLIANCE VIOLATIONS**. Pharmacists should not agree to serve as PIC if they cannot adequately supervise and monitor the pharmacy. The Board's website contains additional resources for PICs, including, a Pharmacy Self-Assessment Guide that can be used to assess the pharmacy's compliance status before an inspection.

Extended Leave: If a PIC will be on extended leave (i.e., vacation, maternity leave), the PIC and permit holder should review the pharmacy's operations to determine if a new PIC should be named. If a new PIC is named, an official Pharmacist-In-Charge Change application must be filed. A second Pharmacist-In-Charge Change application must be filed when the previous PIC returns to work and resumes PIC duties. Both PIC changes would require a separate controlled substance inventory.

Under § 338.210.5, the PIC is responsible for pharmacy compliance even if pharmacy policies/procedures are set corporately or by the pharmacy's owners. Compliance violations could result in disciplinary action against the PIC's pharmacist license as well as the pharmacy's permit.

C.6 PHARMACY SUPERVISION

A pharmacist must be present and on duty at all times when the pharmacy is in operation or when prescriptions are being compounded, prepared, distributed or dispensed. Pharmacy technicians may assist in any area of pharmacy practice. However, technicians may not work independently and must be under the "direct supervision and responsibility" of a Missouri-licensed pharmacist at all times. [20 CSR 2220-2.700].

When no pharmacist is on duty, a sign must be posted on the prescription counter and on all entrance doors informing the public that "no pharmacist is on duty." Sign lettering may be no smaller than two inches (2") in height. [20 CSR 2220-2.010(1)(A)]. The "no pharmacist on duty sign" does not have to be posted if the pharmacist is in the pharmacy building but briefly absent from the pharmacy area (i.e., restroom breaks).

Remote supervision of pharmacy technicians is not allowed in Missouri.

C.7 POLICIES AND PROCEDURES

Generally, Missouri law requires the following pharmacy policies and procedures:

Policy/Procedure Type	Regulation	Annual Review Required
General	20 CSR 2220-2.090 (2)(P)	
Class C: Long Term Care	20 CSR 2220-2.145	
Class E: Radiopharmaceutical	20 CSR 2220-2.500	
Class F: Renal Dialysis	20 CSR 2220-2.600	
Class H: Sterile Products Compounding	20 CSR 2220-2.200	✔
Class I: Consultant	20 CSR 2220-2.010 (10)	
Class J: Shared Service	20 CSR 2220-2.650	
Class L: Veterinary	20 CSR 2220-2.675	✔
Class M: Specialty (Bleeding Disorder)	20 CSR 2220-6.100	✔
Classes N & O: Automated Dispensing System	20 CSR 2220-2.900	
Technician Duties	20 CSR 2220-2.090(2)(CC)	
Prescription Deliveries	20 CSR 2220-2.013(1)	
Administration by Medical Prescription Order	20 CSR 2220-6.040	✔
Electronic Record keeping Systems	20 CSR 2220-2.083	✔
Automated Filling Systems	20 CSR 2220-2.950	✔

Note: Additional policies and procedures may be required by other state/federal law (i.e., DEA, BNDD).

Effective policies and procedures promote consistency and prevent compliance violations when shared with and practiced by pharmacy staff. Policies/procedures should be reviewed on a regular basis and updated as needed. Relevant changes should be shared and discussed with pharmacy staff to ensure compliance. Policies and procedures can be maintained electronically but must be readily retrievable during an inspection.

C.8 SECURITY

Pharmacies must maintain adequate security to deter drug theft/diversion. [20 CSR 2220-2.010(1)(H)]. Pharmacies located in facilities that have public access after the pharmacy's normal hours of operation must also have sufficient alarm systems or locking mechanisms that are able to detect and prevent unauthorized access into the pharmacy (i.e., access via the ceiling or above gates/doors). Licensees should consider counter heights, wall/ceiling barriers and ease of public access when assessing the pharmacy's security. The Board has received multiple reports of medication being stolen by customers who were able to reach into will-call bins or over prescription counters. *Note: Licensees must also comply with all controlled substance security requirements.*

Additional diversion prevention tips and resources are available on the Board's website.

Resources and video training materials on preventing or handling pharmacy robberies can be found online at http://www.rxpatrol.com/. This website is provided for informational purposes only and is not sponsored or endorsed by the Board.

C.9 LICENSE POSTING

The pharmacy's permit and the licenses/registrations of all pharmacists, intern pharmacists and technicians working in the pharmacy must be conspicuously displayed in the pharmacy area. [20 CSR 2220-2.010(1)(K)]. Pharmacist licenses must be accompanied by a 2"x 2" photo. In lieu of posting, pharmacists working at more than one pharmacy must have proof of licensure in their possession (i.e., license wallet card, online license verification). [20 CSR 2220-2.010(1)(L)].

Pharmacies are also required to maintain a list of all pharmacy technicians authorized to access the pharmacy and their duties, as well as a policy and procedure manual for technician supervision. [20 CSR 2220-2.090(2)(BB), (CC)]. The list should be regularly reviewed to make sure it is current and updated.

C.10 OFFICE WAREHOUSE/STORAGE SITES

Pharmacies must register with the Board any site/facility used to store medication or confidential pharmacy records offsite at an address or premises that is separate from the main pharmacy. [20 CSR 2220-2.010(1)(I), (J)]. An online Warehouse/Storage Site Notification Form is available on the Board's website.

Off-site record storage locations must meet the following requirements:

- Adequate security must be maintained to protect confidentiality and prevent unauthorized access. At a minimum, the off-site location must be equipped with an alarm system;
- No record less than two years old may be stored off site;
- Security breaches must be reported to the Board within fifteen (15) days; and
- All records stored off site must be made available for inspection within two business days, if requested.

Pharmacies may share storage space if each pharmacy's records and/or drug inventory can be individually identified and are securely stored to prevent unauthorized access. *Note: Offsite storage would include storing records at another pharmacy and would require notification to the Board.*

C.11 STAFFING RATIOS

Missouri does not require mandatory staffing ratios (i.e., pharmacist-to-technician). However, the Board is concerned about the quality of services if staffing levels are inadequate for appropriate oversight and patient care. Licensees are strongly cautioned to maintain appropriate staffing levels to ensure public safety.

C.12 CHANGE OF OWNERSHIP

Pharmacy permits are issued for a named permit holder and are not transferable. Accordingly, a permit becomes void on the effective date of an ownership change and a new pharmacy permit is required for the new owners. [20 CSR 2220-2.020(3)]. Once a completed Change of Ownership Permit Application has been filed, the Board may issue a temporary pharmacy permit to allow the new ownership to continue operating until a new permit is issued.

- *Sole Proprietors:* A pharmacy owned by a sole proprietor will be deemed to have changed ownership if: 1) the proprietor enters into a partnership with another individual or business entity, or 2) the proprietor dies. [20 CSR 2220-2.020(3)].
- *Corporations, LLCs, LLPs:* A new pharmacy permit is required if a corporation, limited liability partnership ("LLP"), or limited liability company ("LLC") begins or transfers ownership of a pharmacy. A new permit is required regardless of the relationship between the previous and subsequent owners.

A Change of Ownership application is not required if:

- The pharmacy is owned by a corporation and the owners of the stock change. However, individuals/entities must notify the Board in writing within thirty (30) days of acquiring more than twenty-five percent (25%) of a pharmacy's ownership, or;
- The members or partners of a LLP or LLC change, as long as the partnership or company is not dissolved by the change. Partner/member changes must be reported to the Board in writing within ten (10) days after the change. [20 CSR 2220-2.020(3)].

A new or amended controlled substance registration may also be required.

C.13 CHANGE OF LOCATION/REMODELING

Pharmacy permits are only valid for the address identified on the permit. A Pharmacy Location Change application must be filed with the Board before the pharmacy moves to a new location. [20 CSR 2220-2.020(4)]. The application must be approved and the premises must be inspected prior to operation (inspection is required for in-state pharmacies). If approved, the Board will issue a permit for the new location with the previous permit number. *Note: Permit holders should notify the Board in writing if the pharmacy's address changes but not the location. An amended permit will be issued without charge.*

Remodeling: A Pharmacy Location Change application is not required for remodeling within an existing structure. However, permit holders must file an affidavit that includes a description of the proposed changes and the projected completion date. [20 CSR 2220-2.020(4)(A)]. The remodeling affidavit and project plans must be filed with the Board no

later than thirty (30) days before the changes begin. Rule 20 CSR 2220-2.020(4)(A) defines remodeling as: 1) any change in the storage conditions of Schedule II substances, 2) any new connections to water/sewer resources, or 3) any changes in the overall physical security of drugs stored in the pharmacy.

A move outside the existing building to a temporary structure during a facility renovation is considered a change of location. A move back to the renovated area is considered a second location change. Both moves require a separate Location Change application (and an inspection for resident pharmacies).

Licensees should check with BNDD and the DEA to determine if a new or amended controlled substance registration is also required.

C.14 NON-RESIDENT PHARMACIES

Pursuant to 20 CSR 2220-2.025, pharmacies located outside of Missouri may not ship, mail or deliver a filled prescription/medication order into Missouri without first obtaining a Missouri pharmacy permit.

To be eligible for licensure, a non-resident pharmacy must be located in the United States or a U.S. territory and have a current and active pharmacy license in the state/territory where the non-resident pharmacy is physically located. [20 CSR 2220-2.025]. Non-resident pharmacies must designate a pharmacist-in-charge who will be personally responsible for supervising the pharmacy and who holds an active pharmacist license in Missouri or in the non-resident pharmacy's licensing state/territory. A non-resident pharmacy may not renew their license if the pharmacy no longer holds a valid pharmacy license/permit in their home state. [§ 338.270] *Note: For non-resident licensure exemptions see 20 CSR 2220-2.025(1).*

C.15 TERMINATION OF BUSINESS

Prior to terminating business, the PIC and the permit holder should ensure proper arrangements have been made for all inventory and pharmacy records. An Out-of-Business Notification Form must be filed with the Board within fifteen (15) days after the permit holder stops operating. [20 CSR 2220-2.015(1)]. The pharmacy's permit must also be returned to the Board.

The closing pharmacy may transfer or dispose of medication in accordance with state and federal law. [20 CSR 2220-2.015(2)]. A drug distributor license is not required for a one-time transfer of medication/devices if the pharmacy is terminating business. [20 CSR 2220-2.015(3)]. Pharmacies may not transfer misbranded, outdated or adulterated drugs, except for proper disposal.

A complete inventory of all controlled substances transferred or disposed of must be completed on the termination date. [20 CSR 2220-2.015(2)(A)]. If controlled substances are transferred to another pharmacy, the inventory will serve as the final inventory for the terminating pharmacy and the initial inventory for the receiving entity. A copy of the inventory must be included in the records of each permit holder involved in the transfer. Controlled substances must be transferred via invoice or, if applicable, a written/electronic DEA-222 form.

Records: The closing pharmacy must designate a secure location where pharmacy records will be kept after the pharmacy is closed. The Board recommends informing patient of where/how to locate prescription records in the future. Records transferred to an unlicensed location must be retrievable within seven (7) working days of a Board request. [20 CSR 2220-2.015(1)(C)].

C.16 NON-DISPENSING ACTIVITIES

Generally, the practice of pharmacy may only be performed on the premises of a Missouri-licensed pharmacy. However, 20 CSR 2220-6.055 allows a Missouri-licensed pharmacist to perform the following non-dispensing activities outside of a licensed pharmacy:

1) *Patient counseling/education*
2) *Obtaining patient history/information*
3) *Reviewing patient records/medical histories*
4) *Patient assessment/evaluation, as authorized by Missouri law*
5) *Billing and insurance claim submissions/ review*
6) *Drug utilization review*
7) *Assessing payor eligibility/coverage*
8) *Pharmacy compliance audits/evaluations*
9) *Administering drugs, vaccines, or biologicals, as authorized by law and the rules of the Board*
10) *Peer review/peer consultations*
11) *Reviewing, selecting, and developing formularies or plan/practice guidelines*
12) *Reviewing compliance with benefit guidelines*
13) *Managing inventory, including purchasing and ordering*
14) *Managing/reviewing information systems*
15) *Patient medication review*
16) *Consulting with other health care professionals*
17) *Patient referrals*
18) *Medication therapy management*
19) *Prescription order entry/review, provided that a pharmacist may only accept a prescription on the premises of a Missouri licensed pharmacy*

Pharmacists operating under 20 CSR 2220-6.055 are prohibited from meeting with patients in the pharmacist's residence or living quarters.

The Board is frequently asked if a pharmacist in another state can be used to perform DUR or prescription order review for a Missouri licensed pharmacy. A pharmacist may perform non-dispensing activities at a facility located outside of Missouri for, or on behalf of, a Missouri pharmacy if:

- The individual is a Missouri licensed pharmacist, or
- The facility is licensed as a Missouri pharmacy and is operating under a Class J Shared Services arrangement.

A pharmacy permit would be required if a pharmacy technician will be assisting at a non-pharmacy location with non-dispensing activities other than immunization.

C.17 MANDATORY REPORTING OF PHARMACIST DISCIPLINE

Pursuant to § 383.133, RSMo, any entity that employs a pharmacist to provide health care services must report to the Board:

- Any final disciplinary action against the pharmacist that might have led to disciplinary action under § 338.055, RSMo, or
- The voluntary resignation of any pharmacist against whom any complaints or reports have been made which might have led to disciplinary action.

"Final" disciplinary action would include any final action to reprimand, discipline or restrict a pharmacist's practice if the activities underlying such action would constitute grounds for licensee discipline under § 338.055, RSMo.

The reporting requirement applies to any entity that employs a pharmacist to provide health care services, including, but not limited to, pharmacies, hospitals, ambulatory surgical centers, long-term care facilities, or nursing homes. Reports must be submitted within 15 days of the final disciplinary action/resignation. [§ 383.133.2, RSMo]. Reporting is not required if the disciplinary action is not "final."

Interested parties should consult legal counsel to determine what disciplinary actions/voluntary resignations must be reported. In the past, the Missouri Administrative Hearing Commission has found legal grounds for the Board to impose discipline under § 338.055, RSMo, for the following types of conduct:

- *Practicing without a license*
- *Falsifying prescriptions*
- *Altering a prescription without authorization*
- *Immunizing without a protocol*
- *Diverting medication*
- *Compounding for office stock*
- *Dispensing without a valid prescription*
- *Theft of merchandise, gift cards, food or other items*
- *Violating state/federal controlled substance laws*
- *Unsupervised technicians*
- *Unlicensed practice*
- *Impairment/Illegal drug use*
- *Disciplinary action by BNDD, DEA or another state/federal agency*
- *Allowing unlicensed technicians or interns to practice*

This list is provided for informational purposes only and is not exhaustive. Additional grounds for discipline exist under § 338.055, RSMo, that are not listed above.

Reports can be filed online at https://renew.pr.mo.gov/pharmacists-disciplinary-action-report.asp or mailed to: Missouri Board of Pharmacy, P.O. Box 625, Jefferson City, Missouri 65102. Online reports are requested.

C.18 CLASS-B HOSPITAL PHARMACY

In 2014, the Missouri legislature amended § 338.220, RSMo, to change the previous "Class B Hospital Outpatient Pharmacy" permit classification to a "Class B Hospital Pharmacy." A Class B Hospital Pharmacy is now defined as a pharmacy owned, managed, or operated by a hospital as defined by § 197.020 or a "hospital clinic or facility" that is under common control, management or ownership of the same hospital or hospital system. [§ 338.165.1(3)].

As licensed Missouri pharmacies, a Class B pharmacy can provide pharmacy services to the general public, including, to hospital staff and hospital outpatients. A separate Class A Community/Ambulatory pharmacy permit is not required. However, a specialized permit classification would be required for any specialty pharmacy services (i.e., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).

Section 338.220, RSMo, grants two new allowances to Class B Hospital pharmacies: (1) Class B Hospital pharmacies may dispense medication by prescription or by medication order, and (2) Class B Hospital pharmacies may distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

The Board has issued a separate Class-B Pharmacy Guidance document. Licensees should review the Guidance for additional Class-B compliance information.

The Missouri Department of Health and Senior Services (DHSS) has jurisdiction over, and regulates, pharmacy services provided within the premises of a DHSS licensed hospital. The Board does not regulate pharmacy services under DHSS' jurisdiction. Hospitals should contact DHSS at (573) 751-6303 for hospital compliance information/questions.

C.19 CLASS-J SHARED SERVICES

Pharmacies engaged in shared services with another pharmacy must have a Class-J pharmacy permit. Specifically, a Class-J permit is required if a pharmacy will be using, or assisting another pharmacy with:

- Filling or refilling a prescription drug order, or
- Performing or assisting in the performing of any function associated with the dispensing process. This would include drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions for another pharmacy.

Pharmacies may participate in a Class-J shared services arrangement if both pharmacies:

1) Have the same owner or have a written contract outlining the shared services to be provided by, and the responsibilities of, each party; and
2) Maintain separate pharmacy licenses for each shared services location; and
3) Share a common electronic file that allows access to sufficient information necessary or required to fill/refill a prescription drug order. The pharmacies must share a record keeping system that provides real time, on-line access to shared services by both pharmacies.

Class-J pharmacies must also maintain a policy and procedure manual that describes/includes procedures for:

1) How the parties will comply with state/federal requirements;
2) Identifying the pharmacist responsible for dispensing and counseling,;
3) Tracking the prescription drug order during each step in the process;
4) Maintaining adequate security to protect the confidentiality and integrity of patient information; and
5) Maintaining a quality assurance program for pharmacy services that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and resolve identified problems. The policy and procedure manual must be manually or electronically maintained at each participating pharmacy.

Once again, a Class-J permit is required for both pharmacies engaged in shared services. Pharmacies may add a classification by filing a Pharmacy Classification Change Application with the applicable fee.

Transferring prescription information between Class-J pharmacies that share a real-time, on-line database are not considered "prescription transfers" under 20 CSR 2220-2.120. Other controlled substance laws may apply.

C.20 Class-L Veterinary Pharmacy

Pharmacies with a Class-A or Class-B pharmacy permit may dispense or provide legend drugs for both animal and human use. In 2012, Missouri law was amended to establish a Class-L Veterinary pharmacy permit for entities only dispensing or providing legend drugs for animal use. Class-L pharmacies must comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board. However, rule 20 CSR 2220-2.675 establishes additional exemptions/allowances to accommodate Class-L dispensing.

Specifically, 20 CSR 2220-2.675 establishes the following exemptions/allowances for Class-L pharmacies:

- Class-L pharmacies may operate without a pharmacist physically present on-site, provided the PIC reviews the activities and records of the pharmacy's operations on a monthly basis. This exemption does not apply if controlled substances or stored, dispensed or provided (See Pharmacy Supervision below);
- Non-controlled legend drugs can be dispensed/filled without a pharmacist present, provided the PIC reviews the pharmacy's dispensing records on a monthly basis (see Dispensing Without a Pharmacist below);

- In lieu of a separate and distinct pharmacy area, Class-L services can be provided in the same space or area as other operations/activities provided there is a defined area for storing legend drugs.The defined drug area must be clean and sanitary and legend drugs must be properly identified at all times. Additionally, medication must be stored within the appropriate temperature requirements as provided by the manufacturer or the latest edition of USP; and
- Class-L pharmacies must have appropriate sewage disposal and a hot and cold water supply. The required water supply may be located outside of the pharmacy area provided the water supply is accessible to pharmacy staff (This exemption does not apply if compounding is performed. Class-L pharmacies engaged in non-sterile or sterile compounding must have a hot and cold water supply within the pharmacy). [20 CSR 2220-2.675(4)(F)]

Once again, the above exemptions/allowances only apply to Class-L pharmacies providing legend drugs for animal use. An additional pharmacy permit would be required to dispense any other legend drug or device.

Class-A and Class-B pharmacies may provide legend drugs for animal use under their Class-A/Class-B permit. However, the exemptions/allowances in 20 CSR 2220-2.675 only apply to Class-L pharmacies. A Class-L classification would need to be added to a Class-A/Class-B permit to use the above exemptions/allowances.

Prescription Requirements: To be valid for dispensing, prescriptions for animal use must comply with § 338.056, RSMo, and § 338.196. Additionally, prescriptions must include:

1) The client's/owner's name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;
2) The prescriber's name, if an oral prescription, or signature, if a written prescription;
3) Name, strength, and dosage form of drug and directions for use;
4) The number of refills, when applicable;
5) The quantity prescribed in weight, volume, or number of units;
6) The address of the prescriber and the patient when the prescription is for a controlled substance;
7) Whether generic substitution has been authorized; and
8) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance. [20 CSR 2220-2.675(7)]

Controlled substance prescriptions must also comply with state/federal controlled substance laws. Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the Board (see Section H).

Labeling: Legend medication for animal use must be labeled in accordance with § 338.059, RSMo. Labels must also include:

1) The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and
2) If applicable, the veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal(s). [20 CSR 2220-2.675(9)]

Labels may be electronically or manually written/numbered.

Pharmacy Supervision: 20 CSR 2220-2.675(6) provides a Class-L pharmacy may operate without a pharmacist on-site, provided the PIC reviews the pharmacy's records and activities on a monthly basis to ensure compliance with state and federal law. The date of the required monthly PIC review must be documented in the pharmacy's records.

This exemption does not apply if the pharmacy sells, dispenses or otherwise provides controlled substances.A pharmacist must be present during pharmacy operations if controlled substances are provided or dispensed. Additionally, a pharmacist must be present whenever compounding is performed (sterile or non-sterile).

Dispensing without A Pharmacist: Class-L pharmacies may accept, fill, enter or dispense non-controlled legend

drugs in the absence of a pharmacist.The pharmacy must have specific policies and procedures for accepting or filling prescriptions/veterinarian orders without a pharmacist as well as policies and procedures for reporting and handling dispensing errors. All dispensing errors must be reported to the PIC within twenty-four (24) hours.

This exemption does not apply to controlled substances. All controlled substances must be verified by a pharmacist before dispensing.

Patient/client counseling must be offered each time medication is dispensed/provided by a Class-L pharmacy, as required by 20 CSR 2220-2.190. If the pharmacist is not on-site, a written offer to counsel with a toll-free telephone number for contacting a pharmacist must be provided.

The PIC must review the prescription records for all legend medication provided without a pharmacist present on a monthly basis. The PIC should be designated as the dispensing pharmacist for these prescriptions/orders unless verified by another pharmacist. The date of the required monthly PIC review must be documented in the pharmacy's requirements.

Compounding: Compounding of legend drugs may only be performed when a pharmacist is on site. Compounding must comply with 20 CSR 2220-2.200 (non-sterile compounding) and 20 CSR 2220-2.400 (sterile compounding).

Controlled Substances: Class-L pharmacies must comply with all state/federal controlled substance laws, including, all security and prescription/order requirements.A pharmacist must be present and onsite during pharmacy operations if controlled substances are sold or provided.

Policies and Procedures: Class-L pharmacies are required to maintain a policy and procedure manual that includes policies/procedures for:

1. Accepting, compounding, dispensing, or filling prescriptions;
2. Accepting, dispensing, or filling prescriptions in the pharmacist's absence;
3. Drug storage and security;
4. Handling drug recalls;
5. Offering patient/client counseling;
6. If applicable, procedures for dispensing or providing prescriptions in a pharmacist's absence;
7. Contacting the pharmacist-in-charge for consultation during the pharmacy's business operations or in the event of an emergency; and
8. Reporting and handling dispensing errors, including, provisions for notifying the PIC of dispensing errors within the required twenty-four (24) hours.

The policy and procedure manual must be reviewed annually by the PIC and must be available on inspection or at the request of the Board.

C.21 Class M Specialty (Bleeding Disorder)

A Class-M pharmacy permit is required for pharmacies providing or offering to provide blood-clotting factor or products to patients with bleeding disorders.As detailed below, § 338.400, RSMo, and rule 20 CSR 2220-6.100 contain additional compliance requirements for:

- Class-M pharmacies dispensing blood-clotting factor concentrates; and
- Class-M pharmacies dispensing blood clotting products to "established patients" or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients

Dispensing Blood-Clotting Factor Concentrates

Class-M pharmacies dispensing blood-clotting factor concentrates to new or existing patients are required to comply with the following:

1) Barring extenuating circumstances, blood clotting factor concentrates must be dispensed within plus or minus ten percent (+/- 10%) of prescribed assays, or as otherwise authorized or directed by the prescriber. [20 CSR 2220-6.100(2)(E)].
2) Prescription Changes/Substitutions: As with all medication, prescriptions for blood-clotting factor concentrates must be dispensed as written or as authorized by the prescriber. If the prescriber authorizes the pharmacy to change or substitute the blood-clotting factor concentrate originally prescribed, the patient/patient's designee must be notified and counseled regarding the change or substitution prior to dispensing via the patient's identified preferred contact method (see below). Counseling is mandatory unless refused by the patient/designee. [20 CSR 2220-6.100(2)(A)].
3) Automatic Refills: Unless previously authorized by the patient or the patient's designee, the pharmacy must contact the patient for authorization to dispense prior to shipping a refill of any blood-clotting product. Authorization may be given verbally or in writing. The authorization date must be documented in the pharmacy's prescription records. The Board also recommends documenting the method/manner of authorization (e.g., written or verbal). [20 CSR 2220-6.100(2)(D)].
4) Delivery Requirements: If requested, blood-clotting factor concentrates must be shipped and delivered to the patient within two (2) business days for established patients in non-emergency situations and three (3) business days for new patients. Non-emergencies include, but may not be limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices must be used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements. [20 CSR 2220-6.100(2)(B)].
5) Pharmacy Contact:A toll free number for the pharmacy must be provided to patients to report problems with a delivery or product. The toll free number must be provided each time a prescription is dispensed (both new and refill). [20 CSR 2220-6.100(2)(C)].
6) Preferred Contact Method: The patient or the patient's designee must be asked to designate a preferred contact method for receiving notifications in the event of a recall or withdrawal of the concentrate dispensed or any related ancillary infusion equipment and supplies. [20 CSR 2220-6.100(2)(C)]. The preferred contact method must be documented in the patient's prescription records.
7) Recall/Withdrawal Notifications: Licensees must notify the patient and the prescriber within twenty-four (24) hours after notification from the manufacturer or from any state/federal entity of a recall or withdrawal of any concentrate or ancillary infusion equipment/supplies. Notification is only required if the manufacturer or state/federal entity requires or recommends patient notification. The pharmacy must contact the prescriber to obtain a new prescription if necessary to dispense a substitute or alternative product.[20 CSR 2220-6.100(2)(F)1.].

If attempts to contact the patient via the preferred contact method are unsuccessful, notification must be mailed to the patient/patient's designee within the required twenty-four (24) hours or the next business day. The time, date, and method(s) of notification must be documented in the pharmacy's records and maintained for two (2) years from the date of recall or withdrawal. [20 CSR 2220-6.100(2)(F)].

Examples of currently known blood-clotting factor concentrates include, but may not be limited to:

- Recombinant Factor VII & Recombinant-activated Factor VIIa;
- Recombinant Factor VIII & plasma-derived Factor VIII;
- Recombinant Factor IX & plasma-derived Factor IX;
- von Willebrand factor products;
- Bypass products for patients with inhibitors;
- Prothrombin complex concentrates; and
- Activated prothrombin complex concentrates.

As currently approved by the FDA blood-clotting factor concentrates do not include:

- Aminocaproic Acid;
- Desmopressin Acetate;
- Warfarin; and
- Heparin

Dispensing Blood-Clotting Products

20 CSR 2220-6.100(3) establishes requirements for Class-M pharmacies dispensing blood clotting products to "established patients" or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients.Section 338.400(4), RSMo, defines a "blood-clotting product" as:

> *A medicine approved for distribution by the federal Food and Drug Administration that is used for the treatment and prevention of symptoms associated with bleeding disorders, including but not limited to recombinant Factor VII, recombinant-activated Factor VIIa, recombinant Factor VIII, plasma-derived Factor VIII, recombinant Factor IX, plasma-derived Factor IX, von Willebrand factor products, bypass products for patients with inhibitors, prothrombin complex concentrates; and activated prothrombin complex concentrates;*

Except as otherwise provided by § 338.400, RSMo, a "blood clotting product" does not include medical products approved solely for the treatment or prevention of side effects of a blood-clotting drug or medication. [20 CSR 2220-6.100(1)(B)].

An "established patient" is defined as a bleeding disorder patient that has been dispensed a legend blood-clotting product by the pharmacy on more than three (3) occasions in a single calendar year. [20 CSR 2220-6.100(1)(C)]."Bleeding disorder" is defined as:

> *A medical condition characterized by a deficiency or absence of one (1) or more essential blood-clotting components in the human blood, including all forms of hemophilia, acquired hemophilia, von Willebrand's disease, and other bleedingdisorders that result in uncontrollable bleeding or abnormal blood-clotting. [20 CSR 2220-6.100(1)(A)]*

A "bleeding disorder" does not include bleeding conditions secondary to another medical condition or diagnosis, except for acquired hemophilia. [20 CSR 2220-6.100(1)(A)].

Class-M pharmacies that meet the above definitions have to comply with the following:

1) Board Notification: The pharmacy must notify the Board annually if the pharmacy intends on providing legend blood-clotting products to bleeding disorder patients. Notification must be made on or before January 31st of each year and should be submitted online at: http://pr.mo.gov/pharmacists-onlineservices.asp. [20 CSR 2220-6.100(3)(A)].
2) Pharmacist Availability: A pharmacist must be available twenty-four (24) hours a day, seven (7) days a week, every day of the year, either on-site or on call, to fill prescriptions for blood-clotting products, within the shipping/delivery time frames referenced below. [20 CSR 2220-6.100(3)(C)].
3) Supply Requirements: The pharmacy must identify, or make arrangements with, a supplier(s) who can provide all brands, assays and vial sizes of FDA approved blood-clotting products, including both, plasma and recombinant products. A list of identified suppliers must be maintained at the pharmacy and available during inspection. Products do not have to be pre-purchased. Instead, the pharmacy must have an identified supplier if a product is needed. [20 CSR 2220-6.100(3)(B)].
4) Ancillary Supplies: Ancillary equipment and supplies required to infuse blood-clotting products intravenously must be available for purchase, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs. Items must be restocked in a reasonable amount of time but in no event later than seven (7) calendar days. [20 CSR 2220-6.100(3)(H)].

5) Shipping/Delivery Requirements: If requested by an established patient, the pharmacy must provide for the shipment and delivery of blood-clotting products to the patient within two (2) business days after receiving a prescription or refill request. For new patients, shipment/delivery must be made within three (3) business days. In the event of an emergency, established patients must be provided access to blood-clotting products within twelve (12) hours after notification from the prescriber that an emergency supply is needed. Emergency requests must be documented in the pharmacy's records.

   If the pharmacy is waiting for action from a third-party payor prior to shipping/delivery (i.e. authorization, certification, etc.), the patient must be notified that the prescription is ready and explain any alternate payment options. Notification must be made as soon as reasonably practicable but in no event later than the required delivery timeframe. Pharmacies may delay shipping/delivery until payment is confirmed.
6) Pharmacist Training/Continuing Education: Pharmacists engaged in dispensing or filling blood-clotting factor concentrates for established patients or who provide patient counseling on blood clotting factor concentrates to bleeding disorder patients must have sufficient knowledge, experience and training to perform the duties assigned. Additionally, pharmacists engaged in counseling bleeding disorder patients must complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment/ therapy or blood-clotting disorders or diseases each biennial renewal period. [20 CSR 2220-6.100(3)(D)].The required CE hours can be used to meet the biennial pharmacist CE requirements.Note:The additional CE is only required for pharmacists engaged in dispensing or filling blood-clotting factor concentrates for "established patients"(see definition above) or who provide patient counseling on blood clotting factor concentrates to bleeding disorder patients.
7) Hazardous Waste: Hazardous waste disposal containers must be provided or available for purchase at the pharmacy (i.e.,- Sharp containers). [20 CSR 2220-6.100(3)(G)].
8) National Register: The pharmacy must register with the National Patient Notification System, or its successor, to receive recall notifications for all products included in the National Patient Notification System. Registration is free and may be completed online at http://www.patientnotificationsystem.org/. Contact information must be kept current and accurate. [20 CSR 2220-6.100(3)(K)].
9) Nursing Services: Contact information must be available for a nurse/nursing service with experience in providing infusion related nursing services or nursing services for bleeding disorder patients, if the nursing services are not provided by the pharmacy. [20 CSR 2220-6.100(3)(I)].
10) Insurance Information: If requested, the pharmacy must explain any known insurance copayments, deductibles, coinsurance payments or lifetime maximum insurance payment limits. [20 CSR 2220-6.100(3)(J)]. The Board recognizes that licensees may have limited access to or knowledge of benefit information. 20 CSR 22206.100(3)(J) provides the pharmacy may rely on information supplied by the patient's insurer.
11) Policy & Procedure Manual: The pharmacy must establish a written policy & procedure manual to ensure compliance with § 338.400 and 20 CSR 2220-6.100. Required policy & procedures include policies/procedures for: processing prescriptions, partial fills, providing/documenting recall notifications, emergency dispensing and cold chain management/packaging (This list is not exclusive; See 20 CSR 2220-6.100(4) for all policy and procedure requirements).Policies and procedures must be reviewed annually.Documentation of the annual review must be maintained in the pharmacy's records. [20 CSR 2220-6.100(4)].

D.1 GENERAL REQUIREMENTS

Except as otherwise provided by state or federal law, licensees may only dispense medication pursuant to a "prescription" or "prescription drug order" from an authorized prescriber for a specific patient. [§ 338.095]. Class B pharmacies are also authorized to dispense by medication prescription order (See C.18). For purposes of Chapter 338, RSMo, and the Board's rules, a "prescription" or "prescription drug order" is defined as:

> *A lawful order for medications or devices issued and signed by an authorized prescriber within the scope of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104, RSMo, to and for the ultimate user. The terms "prescription" and "drug order" do not include an order for medication requiring a prescription to be dispensed, which is provided for the immediate administration to the ultimate user or recipient. [§ 338.095].*

Licensees may only change or modify an OTC product by prescription. Flavoring an OTC product by incorporating a flavoring agent requires a prescription.

D.2 AUTHORIZED PRESCRIBERS

To be valid for dispensing, a prescription must have been written by a prescriber that is licensed in the United States or a U.S. territory who is legally authorized to prescribe. [§ 338.095; 20 CSR 2220-2.020(11)]. Missouri law recognizes the following prescriptive authority:

PRESCRIBER	AUTHORITY
Advanced Practice Registered Nurses	Both controlled & non-controlled prescriptive authority if under a collaborative practice agreement with a Missouri licensed physician. See Section D.8.
Physicians, Dentists, Veterinarians, Podiatrists and Optometrists	May prescribe within their scope of practice.
Physician Assistants	Both controlled & non-controlled prescriptive authority if under a supervisory agreement with a Missouri licensed physician. See Section D.8.
Out-of-State Prescribers	Prescriber must be legally authorized to prescribe in the prescriber's licensing state/territory. The prescription may be filled even if similar prescriptive authority is not recognized in Missouri. (i.e., out-of-state chiropractors, pharmacists or psychologists with prescriptive authority).
Non-U.S. Prescribers	Prescriptions from a prescriber licensed in a foreign country or jurisdiction (i.e., Canada, Mexico) cannot be filled unless the practitioner is also licensed and legally authorized to prescribe in a U.S. state or territory. [§ 338.095; 20 CSR 2220-2.020(11)].
Military Prescribers	The Board does not have jurisdiction over pharmacy practice on military bases. Prescriptions from a member of the armed forces may be filled by a Missouri pharmacy if the prescription complies with all federal requirements.

Licensees are responsible for ensuring valid prescriptive authority and, if applicable, proper controlled substance authority. The DEA publishes a state listing of controlled substance prescribers at http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf. The National Association of Boards of Pharmacy (NABP) also publishes a state-specific listing in its Annual Survey of Pharmacy Law that can be purchased at https://nabp.pharmacy. *Note: These resources are not maintained by the Board; the Board cannot guarantee their accuracy.*

Self-Prescribing: It is illegal for a physician to prescribe controlled substances for him/herself, unless it is a medical emergency (see § 195.070.5, RSMo). It is not illegal for a physician to prescribe non-controlled drugs for themselves, however, the practice is discouraged by the Board of Healing Arts.

Physicians may prescribe controlled or non-controlled drugs for a family member, as long as the physician maintains the same records for family members as he/she would for any other patient and all other prescription requirements are met. Please consult the Board of Healing Arts for additional guidance.

D.3 PRESCRIPTION FORMS

Pursuant to § 338.056, written prescriptions from a Missouri prescriber must be in two-line format with two signature lines on opposite ends of the bottom of the prescription. A prescriber note indicating "DAW," "brand necessary" or "brand medically necessary" is insufficient. "Dispense as Written" must be printed under the signature line on the right and "Substitution Permitted" printed under the signature line on the left. [§ 338.056].

Prescriptions from non-Missouri prescribers must be in the format approved in the state/territory where the practitioner is licensed.

Faxed prescriptions must be in the required two-line format (See D.10). Two-line format is not required for electronically transmitted prescriptions, however, the prescriber must indicate if generic substitution is authorized. (See also D.11).

Security Paper: Missouri law requires secure paper for prescriptions generated from electronic media and given to the patient. The paper must include security features that will detect or prevent the prescription from being copied or altered (e.g., watermark, microprint, heat detection/rub features). [20 CSR 2220-2.085]. BNDD has confirmed that security paper is strongly recommended but not required for controlled substance prescriptions. *Note: CMS may require tamper resistant paper for Medicaid/Medicare reimbursement.*

D.4 GENERAL PRESCRIPTION REQUIREMENTS

To be valid for dispensing, a prescription must include:

- The date of prescribing;
- The name of the patients or, if an animal, species and owner's name;
- The prescriber's name, if an oral prescription, or written or electronic signature if a written, faxed, or an electronically transmitted prescription. Electronic signatures must comply with 20 CSR 2220-2.085;
- Name, strength and dosage of drug, device or poison prescribed and the directions for use;
- The number of refills, if applicable;
- The quantity prescribed in weight, volume, or number of units;
- An indication of whether generic substitution has been authorized by the prescriber, as required by § 338.056, RSMo, and;

- Any change or alteration made to the prescription based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or substitution authority. [See 20 CSR 2220-2.018].

Controlled substance prescriptions must also include:

- The address of the prescriber and the patient
- The prescriber's Drug Enforcement Administration (DEA) number
- For APRN and PA prescriptions, the name, telephone number and address of both the physician and the prescribing APRN or PA [20 CSR 2220-2.018; 20 CSR 2220-4.200(3)(G)7.]

Changes in prescription orders may only be communicated by the prescriber or a duly authorized representative. Pending further DEA guidance, BNDD has provided the following additional guidance for schedule II controlled substances:

Methods of changing C-II controlled substance prescriptions:

1. A prescriber may provide a written change to the pharmacy that the pharmacy must attach to the original prescription. The written change shall document the date and name of the person authorizing the change. The change may be mailed, emailed, or faxed.
2. The change may be communicated orally. The pharmacy shall record the date, changes, and person authorizing the changes on the front or back of the prescription.

What may be changed/added on a controlled substance prescription with permission	What can never be changed/added
• Date written • Patient's address (complete physical address, not P.O. Box) • Drug form • Drug strength • Quantity to be dispensed • Prescriber's address • Prescriber's DEA number • Directions for use • Substitutions permitted • Refill information • Reasons for extended supplies for Schedule II prescriptions.	• Patient's name • Drug name • Prescriber's name • Prescriber's signature

See BNDD's Interim Schedule II Policy for full guidance.

D.5 PATIENT-PRACTITIONER RELATIONSHIP

Prescriptions must be based on a valid pre-existing patient-practitioner relationship. [20 CSR 2220-2.020(11)]. Additionally, the practitioner must have performed a valid medical examination as required by law. [20 CSR 2220-2.020(11)]. A prescription may not be filled if the pharmacist knows, or should reasonably know under the circumstances, that the prescription was based on an internet-based or telephone questionnaire. [20 CSR 2220-2.020(11)]. See Section D.12 for Telehealth/Telemedicine.

If the pharmacist knows or has reason to believe the patient is not under the prescriber's care at the time the prescription is presented, the pharmacist is required to consult with the prescriber to determine if the prescriber intends for the medication to be dispensed. Confirmation should be documented in the prescription record.

Retired, Deceased & Inactive Prescribers: Missouri law does not definitively address filling/refilling of prescriptions that were validly written before a prescriber passes away or stops practicing. Pharmacists should use their professional judgment in continuing to dispense refills and should advise patients to consult with another practitioner as soon as possible. Contact BNDD for guidance on dispensing controlled substances. See also Section E.17 for Emergency Dispensing options.

D.6 AUTHORIZED SIGNATURES

Non-Controlled Substances: Prescribers may sign a non-controlled prescription either manually or electronically. [§ 338.056]. Licensees may contact the prescriber to obtain an oral prescription if a signature is invalid.

- Manual Signatures: Prescribers may manually sign a prescription in the same manner used for signing a check or other legal document. Rubber-stamped signatures are not valid. The prescriber's staff/agents may prepare the prescription. However, the prescriber must manually sign the prescription before it is issued.
- Electronic Signatures: A prescription may be electronically signed if: a) the prescription has been applied to secure paper that prevents/detects copying or alteration or b) the prescription is faxed to the pharmacy from the prescriber's office or the prescriber's authorized agent. [20 CSR 2220-2.085(2)(D), (E)]. To be valid, the electronic signature must be an exact electronic replica of the prescriber's signature or consist of a confidential digital key code, number or other identifier that denotes prescriber authorization (i.e., "electronically prescribed by John Smith, MD") [20 CSR 2220-2.085(1)(D)]. *[See also D.10- Faxed Prescriptions / D.11- Electronic Prescriptions].*

Controlled Substances: Controlled substance prescriptions must comply with state/federal law. Generally, all paper and faxed controlled substance prescriptions must be manually signed by the prescriber. According to BNDD, digitally scanned signatures are not acceptable. With the exception of Schedule II controlled substances, licensees may obtain an oral prescription if the prescriber's signature is invalid.

D.7 PRESCRIPTION LIMITS (PHYSICIANS)

The following Missouri prescription limits apply (controlled substance guidance provided by BNDD):

	Schedule II Controlled Substances	Schedule III-IV Controlled Substances	Schedule V Controlled Substances	Non-Controlled Substances
Prescription Validity	Six (6) Months	Six (6) Months	One (1) Year	One (1) year
Quantity Limits	30-Days/ 90-Days with documented medical reason	90-Days	90-Days	As prescribed
Refills	May not be refilled	Up to five (5) times within six (6) months	As prescribed	As prescribed

According to BNDD, out-of-state prescribers may prescribe controlled substances according to the authority of their home state (including APRNs and PAs). If the patient is a Missouri patient, the controlled substance quantity limits listed above apply. If the patient is an out-of-state patient, the quantity limits of the prescriber's home state apply. [See § 195.080]

D.8 MID-LEVEL PRACTITIONERS (APRNs & PAs)

Pursuant to Chapter 334, Advanced Practice Registered Nurses (APRNs) and Physician Assistants (PAs) may prescribe both controlled and non-controlled substances if the practitioner has a collaborative practice agreement (APRNs) or a supervisory agreement (PAs) with a Missouri licensed physician. [§334.104; § 334.735.4]. To prescribe controlled substances, both the APRN/PA and the collaborating/supervising physician must have a current BNDD and DEA registration. APRNs & PAs may not purchase, stock, dispense, or administer controlled substances independently.

Prescriptions written by an APRN/PA must include:

- The prescribing APRN's/PA's name, telephone number and address;
- The supervising/collaborating physician's name, telephone number and address;
- The APRN's or PA's signature, and
- For controlled substances, the APRN's or PA's DEA #. [§ 334.735.4, 20 CSR 2200-4.200(3)(G).7.].

Non-controlled prescriptions from APRN & PAs are valid for one year and refills/quantity limits are as prescribed. For controlled substances, BNDD has issued the following guidance *(the following would apply unless otherwise restricted in the governing protocol/supervisory agreement):*

	Advanced Practice Registered Nurses	Physicians' Assistants
Schedule II	• Hydrocodone products only- limited to a 5-day or 120-hour supply. **Includes single ingredient products.*	• Hydrocodone products only- limited to a 5-day or 120-hour supply. **Includes single ingredient products.*
Schedule III (Opiates)	• Limited to a 5-day or 120-hour supply • Prescription valid for 6-months from date written. • No refills allowed***	• Limited to a 5-day or 120-hour supply • Prescription valid for 6-months from date written • No refills allowed***
Schedule III (Non-Opiates)	• Full authority to prescribe • 90-Day quantity limits • Prescription valid for 6-months from date written.	• Limited to a 5-day or 120-hour supply • Prescription valid for 6-months from date written. • No refills allowed
Schedule IV & V	• Full authority to prescribe • 90-day supply limit for a single prescription • Prescription valid for 6-months from date written	• Full authority to prescribe • 90-day supply limit for a single prescription • Prescription valid for 6-months from date written
Family Members	• No authority; Cannot prescribe controlled substances for family members as defined below	• No authority; Cannot prescribe controlled substances for family members as defined below
Self-Prescribing	• No authority; Cannot prescribe for themselves (all schedules)	• No authority; Cannot prescribe for themselves (all schedules)

**** According to BNDD, a new prescription can be written for an additional 5-day supply, however, a new prescription and prescription number would have to be generated. BNDD would consider these new prescriptions and not refills.*

"Family" is defined in the state medical board's rule as a spouse, parent, grandparent, great-grandparent, child, grandchild, great-grandchild, brother, sister, aunt, uncle, nephew, niece, mother-in-law, father-in-law, brother-in-law, sister-in-law, daughter-in-law or son-in-law (adopted and step members are included). [20 CSR 2150-5.100(3)(G)(10)].

In 2014, Missouri law was amended to create a new prescriber class for "assistant physicians." The Missouri Board of Registration for the Healing Arts anticipates assistant physician licensure may begin in 2017. Until such time, assistant physicians are not authorized to prescribe in Missouri. Significantly, "assistant physicians" are different from "physician assistants." PAs are currently licensed in Missouri and are authorized to prescribe with restrictions.

D.9 TELEPHONE PRESCRIPTIONS

Pharmacists may accept a telephone prescription communicated by the prescriber or the prescriber's duly authorized agent. [§ 338.095]. Telephone prescriptions must be promptly reduced to writing or electronically recorded in the pharmacy's prescription records. Telephone prescriptions may be received by a pharmacist or by a technician/intern pharmacist acting under the pharmacist's direct supervision. All prescription information required by 20 CSR 2220-2.018 must be recorded, including, substitution authorization.

D.10 FAXED PRESCRIPTIONS

Faxed prescriptions must be in the required two-line format and include all prescription information required by § 338.056 and 20 CSR 2220-2.018. A true faxed prescription is a full image of a physical prescription document that is faxed to the pharmacy. [20 CSR 2220-2.085(1)(B)]. In other words, the sender must insert a fully completed prescription document into the fax machine and fax the prescription. Faxed prescriptions may only be sent by the prescriber or the prescriber's authorized agent. Pharmacies are not allowed to fill prescriptions faxed by a patient.

Pharmacists should use their professional judgment and take appropriate measures to verify/authenticate faxed prescriptions and their origin such as:

- Maintaining a practitioner fax number reference list or other electronic signature file;
- Verifying the telephone/fax number; or
- Orally verifying with the prescriber's office that the prescription is correct as written and transmitted. [20 CSR 2220-2.085(2)(C)].

The original fax and any other information sent from the electronic source must be readily retrievable [20 CSR 2220-2.085(2)(A)]. Any alteration(s) to the prescription after dispensing must be authorized by the prescriber and documented in the prescription records along with the identity of the pharmacist responsible for the alteration [20 CSR 2220-2.085(2)(A)].

Non-Controlled Substances: Faxed non-controlled prescriptions may be manually signed or electronically signed as authorized by 20 CSR 2220-2.085. To be valid, the electronic signature must be an exact electronic replica of the prescriber's signature or consist of a confidential digital key code, number or other identifier that denotes prescriber authorization (i.e., "electronically prescribed by John Smith, MD") [20 CSR 2220-2.085(1)(D)].

Controlled Substances: Faxed controlled substance prescriptions must be physically signed by the prescriber and must

comply with all BNDD and DEA requirements. The DEA does not allow an electronically signed controlled substance prescription that is generated from a prescriber's software to be converted to fax. See 20 CSR 2220-2.085 and Section D.11 for electronically transmitted prescription requirements.

> *Prescriptions sent electronically from a prescriber's computer software to the pharmacy's fax machine are electronically transmitted prescriptions under the Board's rules and are not considered "faxed prescriptions."*

D.11 ELECTRONIC PRESCRIPTIONS

Non-Controlled Substance Prescriptions: Prescriptions for non-controlled drugs may be transmitted electronically either as an exact visual image of the prescription (e.g., a fax) or in another electronic form (e.g., data transmission or scan). [20 CSR 2220-2.085(1)]. The prescription must be electronically transmitted by the prescriber or the prescriber's authorized agent. Prescriptions electronically transmitted by the patient are not valid for dispensing.

Controlled Substances: Electronic prescribing of controlled substances is allowed in Missouri if the pharmacy and prescriber use software that has been certified to meet DEA requirements. Prescribing must also comply with all DEA electronic prescribing requirements. (See BNDD's rules- 19 CSR 30-1.048(9) and 19 CSR 30-1.062(4)). (See section D.11)

D.12 TELEHEALTH/TELEMEDICINE

In 2016, the Missouri General Assembly enacted Senate Bill 579 which allows Missouri health care providers to provide "telehealth" or "telemedicine" services and also contains requirements for prescriptions issued based on a "telehealth" or "telemedicine" examination. Under the new law, a Missouri pharmacy may fill a prescription that is issued based on a valid "telehealth" or "telemedicine" exam if the prescriber/prescription complies with SB 579. The prescription must also comply with Chapter 338, RSMo, and all other state/federal law (including controlled substance laws).

SB 579 defines "telehealth" or "telemedicine" as:

> *The delivery of health care services by means of information and communication technologies which facilitate the assessment, diagnosis, consultation, treatment, education, care management, and self management of a patient's health care while such patient is at the originating site and the health care provider is at the distant site. Telehealth or telemedicine shall also include the use of asynchronous store-and-forward technology.*

Significantly, telehealth/telemedicine does not include prescribing based solely on an internet or telephone questionnaire or prescribing based on a telephone examination without a valid prescriber-patient relationship.

To be valid, a telemedicine prescription from a Missouri prescriber must meet the following requirements:

- The prescriber must be licensed to practice in Missouri, and
- The prescription must be based on a valid physician-patient relationship, and
- The prescription must comply with all other state/federal prescription requirements, including, 20 CSR 2220-2.018 and § 338.056, RSMo (two-line format), and
- The telemedicine services must be within the provider's "scope of practice" and meet the applicable standard of care.

A telemedicine prescription CANNOT be filled if:

- The prescription was issued based solely on an internet request or an internet questionnaire, or

- No legitimate practitioner-patient relationship exists, or
- The prescription was based solely on a telephone evaluation without a previously established and ongoing prescriber-patient relationship exists.

Pharmacists should use their professional judgment when determining if a valid physician-patient relationship exists. Determining the applicable standard of care will depend on the health care provider's licensing regulations and applicable medical standards. The Board cannot give additional guidance here. However, licensees should be attentive to prescriptions that appear to be outside of the prescriber's scope of practice.

The Board is aware that prescribers frequently issue prescriptions after consulting with a patient over the phone. Once again, SB 579 allows this practice and provides a prescription may be issued based on a telephone evaluation if "a previously ongoing physician-patient relationship exists" between the prescriber and the patient being treated. [Sec. 334.108.3]. This exception would allow prescribers to continue their current practice of consulting with patients over the phone if the provider and patient have a previously established, ongoing relationship.

Mid-Level Practitioners: The new telehealth/telemedicine provisions are applicable to prescriptions issued by "any licensed health care provider" which would include APRNs and PAs acting within their licensed scope of practice. However, mid-level practitioners must comply with all applicable prescribing and collaborative practice requirements.

Controlled Substances: The Ryan Haight Act and federal controlled substance laws include specific requirements for telemedicine and controlled substances. Licensees should consult with legal counsel, the DEA and BNDD to ensure compliance with applicable federal law. The Board cannot give legal advice. The DEA has issued the following caution regarding controlled substances:

> *The pharmacist who deliberately ignores a questionable prescription when there is a reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense which may result in the loss of one's business or professional license."*

BNDD has also issued the following excerpted statement regarding telemedicine and controlled substance activities:

> *The Missouri BNDD has reviewed the telemedicine statutes and discussed them with the Drug Enforcement Administration (DEA). The statutes provide definitions and make determinations on the delivery of telemedicine. As always, a state licensing board would make determinations regarding proper clinical care. For controlled substance prescribing and dispensing, the following issues are relevant:*
>
> - *The controlled substance activity must be by an authorized and registered professional who is acting within their scope of professional practice and within the guidelines of Chapter 195, RSMo and its regulations.*
> - *For Missouri practitioners who will be prescribing, the prescribers must have a professional Missouri license, a Missouri BNDD registration and a Missouri DEA registration. This registration must be at their primary practice location where they spend the most time.*
> - *According to the DEA, pursuant to 21 USC 802(54), if the telemedicine is taking place across state lines, the prescriber must be licensed and also have DEA registrations in both states; the state they are prescribing from and also the state where the patient is. If the patient is an in-patient admitted to a hospital, the hospital may have one of their local practitioners issue the drug orders or the hospital may allow that out of state consulting physician to use the hospital's DEA number pursuant to 21 CFR 1301.22(c).*

Pharmacists play a vital role in preventing prescription fraud and abuse. Licensees are reminded of their corresponding responsibility and should exercise sound professional judgment when determining if a telehealth/telemedicine prescription is legitimate.

Out-of-State Prescribers: The Board understands that the Missouri Board of Registration for the Healing Arts will be reviewing the applicability of SB 579 to out-of-state prescribers. In the interim, licensees are reminded that Board rule 20 CSR 2220-2.020(11) provides:

> *A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire or without a valid preexisting patient-practitioner relationship.*

Prescriptions based solely on an internet-based questionnaire or that are issued without a valid preexisting patient-practitioner relationship are not valid in Missouri and cannot be filled, regardless of the location of the prescriber.

D.13 PRESCRIPTION TRANSFERS (ORIGINALS & REFILLS)

Upon request, a prescription must be transferred if: 1) the prescription is still valid and the number of lawfully allowed refills has not been reached [20 CSR 2220-2.120]. Transfer may be requested by the patient or by another pharmacy at the patient's request. Transfer is mandatory and must be completed within one (1) business day of the patient's request [20 CSR 2220-2.120(3)].

Prescriptions may only be transferred to or from a pharmacy licensed in a U.S. state/territory [20 CSR 2220-2.120(1)]. Prescriptions may not be transferred to an unlicensed entity or a foreign pharmacy (i.e., a pharmacy not located in a U.S. state/territory).

The transferring and receiving pharmacy must record:

TRANSFERRING PHARMACY	RECEIVING PHARMACY
• The name of the pharmacy receiving the transfer; • The transfer date; • The identity of the transferring pharmacist; • The prescription must be immediately voided in the pharmacy's electronic system or the word "void" must be written on the face of the invalidated prescription; and • For controlled substances, the address and DEA registration number of the receiving pharmacy.	• All information required for an original prescription; • An indication that the prescription was transferred from a licensed location; • The date the Rx was originally issued; • The date of original filling, if different from the original issuance date; • The number of refills authorized on the original prescription and the number of remaining authorized refills;* • Date of last refill;* • The prescription label number;* • The licensed pharmacy that transferred the prescription; • The transferring pharmacist, and; • For controlled substances, the address and DEA # number of the transferring pharmacy. * *Not required for original prescription transfers.*

Electronic transfers of non-controlled prescriptions are allowed if the pharmacies are under the same ownership and share the same database. The prescription may be transferred by generating a computer-based report at the transferring pharmacy of the prescription(s) transferred out [20 CSR 2220-2.120(2)(B)8.]. The transfer record must be readily retrievable and must include all information required by 20 CSR 2220-2.120.

If a prescription is transferred, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the pharmacy, the prescription must be treated as a new record, showing the original date written and original expiration date [20 CSR 2220-2.080(9)].

The Board is aware of pharmacies improperly denying transfers due to pharmacy disputes, unpaid patient accounts/bills or early refills. Legally valid transfer requests are mandatory. If the refill is too soon, the transferring pharmacy may call attention to the early refill but cannot refuse to transfer. The receiving pharmacy is responsible for reviewing the prescription before dispensing to prevent unauthorized refills.

Under 20 CSR 2220-2.140(5)(D), refills associated with a nursing home order are not valid for transfer or use outside of the facility.

Controlled Substances: The following general requirements apply to controlled substance refill transfers:

- Schedule II controlled substances may not be transferred. [20 CSR 2220-2.120(1)(B)].
- Schedule III-IV controlled substances may be transferred, however, transfer information may only be communicated between licensed pharmacists. [20 CSR 2220-2.120(1)(D)]. Pharmacy technicians or intern pharmacists may not provide or receive controlled substance transfers.
- Schedule III – V controlled substance prescriptions may only be transferred one time. [20 CSR 2220-2.120(1)(E)]. However, additional transfers are allowed if the pharmacies electronically share a real-time, online database. [20 CSR 2220-2.120(1)(E)].

Pharmacies electronically transferring controlled substance refills need to be aware that 20 CSR 2220-2.120 and DEA regulation 21 CFR 1306.25 require that all information for controlled substance refills must be transferred directly between two pharmacists. The transfer of controlled substance refills without the direct involvement of two pharmacists is prohibited- even if the pharmacies share a common database or have a Class J Shared Services arrangement.

The DEA reiterated their position in the March 31, 2010 Federal Register, page 16268, where the DEA commented: "DEA has never permitted the transfer of controlled substance prescriptions without the involvement of two licensed pharmacists, regardless of whether the two pharmacies share a common database." Licensees should review their transfer procedures to ensure compliance with controlled substance laws.

D.14 PRESCRIPTION NUMBERING

Prescriptions must be consecutively numbered or assigned a unique, readily retrievable identifier. [20 CSR 2220-2.010(2); 20 CSR 2220-2.017]. The Board anticipates further defining a "unique identifier" by rule. In the interim, prescriptions should be uniquely labeled in a manner that allows individual retrieval.

E.1 GENERAL REQUIREMENTS

Licensees may lawfully dispense medication pursuant to a valid patient-specific prescription or a prescription drug order from an authorized prescriber. Class-B pharmacies may also dispense based on a medication order. Intern pharmacists and pharmacy technicians may assist with dispensing, however, all activities must be supervised by a pharmacist. [20 CSR 2220-2.010(1)(B)]. A Missouri-licensed pharmacist must inspect and verify the prescription's accuracy prior to dispensing, including the contents and the affixed label. [20 CSR 2220-2.010(1)(B)]. See E.16 for automated filling systems.

Licensees should take proactive steps to prevent and detect errors. The Board encourages licensees to report dispensing errors to the USP-ISMP Medication Errors Reporting Program. This confidential program gathers and analyzes data to help prevent future errors. Reports may be submitted online at www.ismp.org.

E.2 AUTHORIZED MEDICATION SOURCES

Licensees may only dispense medication that is received from: (1) a Missouri-licensed drug distributor, (2) a Missouri licensed pharmacy or (3) a pharmacy licensed in another U.S. state or territory. If medication is received from a non-resident pharmacy that is not licensed in Missouri, the total amount of medication distributed/received cannot exceed five-percent (5%) of the pharmacy's total annual prescription drug sales. [§ 338.315.2] The receiving Missouri pharmacy must maintain proof the non-resident pharmacy has a current pharmacy license in the state/territory where the drug is shipped/distributed from.

Medication receipts/transfers must be documented by invoice (non-controlled and schedule III-V drugs) or via a DEA 222 form (schedule II drugs). For medication received from a non-resident pharmacy that is not licensed in Missouri, an invoice record must also be maintained which documents the name and address of the non-resident pharmacy, the purchase/transfer date and the name, strength, and quantity of the drug received. *See rule 20 CSR 2220-6.050.1 for additional drug distribution exemptions.*

E.3 DRUG SAMPLES

Unless otherwise allowed by federal law, drug samples may not be dispensed by, or maintained in, the pharmacy. [20 CSR 2220-2.010(8)].

E.4 LABELING

A written label must be affixed to each prescription container dispensed to a consumer indicating:

1) The date the prescription was filled;
2) A prescription number or other unique identifier;
3) The patient's name;
4) The prescriber's directions for usage;
5) The prescriber's name *(see below for APRNs/PAs);*
6) The pharmacy's name and address;
7) The exact name and dosage of the drug dispensed, and;
8) If a generic substitution is made, the manufacturer must be identified on the label or in the pharmacy's records by name or abbreviation. [§ 338.059].

For controlled substance prescriptions issued by APRNs and PAs, the label must include both the names of the prescribing mid-level practitioner and their supervising or collaborating physician. [§ 195.100, RSMo]. *Note: This pertains to "prescriptions" and not to internal drug "orders" for in-patients of a licensed hospital or to out-of-state midlevel practitioners with independent prescriptive authority.*

Missouri law does not prohibit the addition of other label information. However, prescription labels should be clear and easily readable.

E.5 PATIENT COUNSELING

Patients must be offered the opportunity to consult with a Missouri-licensed pharmacist each time a prescription is dispensed (new or refill). [20 CSR 2220-2.190]. If the medication is delivered to the patient, a written offer to counsel must be provided with the patient's medication along with a toll-free telephone number for the dispensing pharmacy. [20 CSR 2220-2.190(1)].

The offer to counsel may be extended by pharmacy staff. However, counseling may only be provided by a Missouri-licensed pharmacist or a Missouri-licensed intern pharmacist acting under the pharmacist's immediate supervision. [20 CSR 2220-2.190].

Patient counseling is not required if:

- The patient is an inpatient of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications, or;
- The patient or caregiver refuses consultation. [20 CSR 2220-2.190(4), (5)].

Counseling should focus on enhancing or optimizing drug therapy and promoting safe/appropriate medication use. [20 CSR 2220-2.190(1)]. At a minimum, pharmacists must provide any counseling required by state/federal law.

To facilitate counseling, licensees are required to collect and maintain appropriate patient information. Appropriate information may include, but is not limited to, the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies and a list of other drugs prescribed. [20 CSR 2220-2.190(2)].

The Board is aware of instances where delivery drivers are personally delivering medication to the patient and verbally offering patient counseling that is subsequently provided by a pharmacist electronically or on the phone. A toll-free number and written offer to counsel is not required in these instances if a verbal offer is given to the medication recipient and the patient is able to consult with a pharmacist either electronically or verbally at the time the prescription is delivered.

E.6 GENERIC SUBSTITUTION [§ 338.056]

Unless otherwise requested by the patient, a pharmacist may substitute a generic equivalent if:

- The drug substituted is not listed as therapeutically inequivalent to the product prescribed in the FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book);
- The generic substitution costs less than the prescribed product; and
- The prescriber authorized substitution. Authorization may be provided orally, electronically or by signing the "Substitution Permitted" line on the prescription. [§ 338.056]. For non-Missouri prescribers, substitution would be governed by the prescriber's licensing state/territory.

If a generic product is substituted, the manufacturer's name or abbreviation must be identified on the prescription label or in the pharmacy's records.

Printing only a brand name on a dispensing label when a generic product is dispensed is misleading to the public and considered misbranding. Some licensees list the generic product on the label and then use the statement "substituted for" with the brand name of the product that is being substituted. This is acceptable if the label is not misleading. However, there is no law requiring that a brand name be on a label when a substitution is made.

E.7 INTERCHANGEABLE BIOSIMILARS [§ 338.055, § 338.056]

Missouri law was amended in 2016 to allow a pharmacist to substitute an interchangeable biological product for a prescribed biological product if substitution has been authorized by the prescriber. [See § 338.055; § 338.056]. An "interchangeable biological product" is defined as a biological product that the Food and Drug Administration:

a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. Section 262(k)(4); or
b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

Pharmacists must inform the patient that an interchangeable biological product has been substituted either verbally or in writing. Additionally, pharmacists must notify the prescriber of the product name and manufacturer either electronically, verbally or in writing within five (5) days of dispensing. Prescriber notification is not required if there is no FDA approved interchangeable biological product for the product prescribed or the prescription is a refill and no changes have been made from the prior filling.

Substitution of interchangeable biological products must comply with all other Board rules applicable to generic substitutions, including, all labeling and recordkeeping requirements.

E.8 CONSOLIDATION OF REFILLS [§ 338.056]

Section 338.202, RSMo, allows a pharmacist to consolidate refills of non-controlled maintenance medication in a single filling. "Maintenance medication" is defined as a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis. To consolidate, the patient must have been previously prescribed the "maintenance medication" for at least a three-month period. Pharmacists may dispense up to the total number of authorized dosage units, however, no more than a 90-day supply may be dispensed at one time.

Consolidation is not allowed if the prescriber indicates on the prescription that dispensing the initial amount followed by periodic refills is medically necessary. Additionally, controlled substances cannot be consolidated.

The Board has been asked if the required 3-month patient use period has to be consecutive. The Board has also been asked if prior fills/refills must have been dispensed by the same pharmacy. Missouri law is silent on both of these questions. Absent further statutory clarification, it appears licensees may consolidate refills for patients prescribed a maintenance medication for any 3-month period even if prior fills/refills were dispensed by another pharmacy.

Pharmacists should exercise their professional judgment when consolidating refills as consolidation may not be appropriate for all patients. The Board suggests advising patients of any additional costs/insurance requirements prior to dispensing.

E.9 OFFICE STOCK DISPENSING

To be valid for dispensing, a prescription must be written by an authorized prescriber for a specific patient. [§ 338.095]. Pharmacies/pharmacists are NOT allowed to dispense drug products for office stock by prescription.

Pharmacies may, however, transfer medication by invoice (non-controlled and schedule III-V drugs) or via a DEA 222 form (Schedule II drugs). *[See E.14 for additional information on drug transfers]*. A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy's total gross sales. Total gross sales are calculated based on the pharmacy's total annual prescription drug sales, or if prescriptions are not sold, 5% of the pharmacy's total drug purchases. [§ 338.330(2); 20 CSR 2220-5.020(1)(B)]. *See C.18 for Class B pharmacy exemptions.*

Pharmacies must be registered with the FDA as a repackager if the pharmacy repackages drugs for distribution to other pharmacies or practitioners.

E.10 PRESCRIPTION DELIVERY SITES

Pursuant to 20 CSR 2220-2.013, prescriptions filled by a Missouri pharmacy "may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy." However, filled prescriptions may be delivered to the following locations at the request of the patient or the patient's authorized designee:

- The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;
- A long-term care facility as defined by 20 CSR 2220-2.140 where the patient resides;
- A hospital, office, clinic or other medical institution that provides health care services;
- A residence designated by the patient or the patient's authorized designee, or;
- The patient's office or place of employment.

Prescriptions may be delivered to other non-pharmacy locations not specified in the rule only if the prescription is delivered directly to the patient or the patient's authorized designee. Patient/designee authorization may be received verbally, electronically or in writing. The Board recommends documenting patient authorization and the requested location in the pharmacy's prescription records. Except as otherwise authorized for long-term care facilities, prescriptions left at a non-pharmacy location cannot be returned to stock if not picked up by the patient.

Rule 20 CSR 2220-2.013 applies to all Missouri licensed pharmacies delivering filled prescriptions regardless of delivery method (i.e., mail order, employee delivery or common carrier).

Pharmacies delivering medication as allowed by the rule must develop written policies and procedures "to ensure the safe and appropriate delivery of prescription drugs within the temperature ranges recommended by the manufacturer" or USP. The Board understands licensees cannot control or predict the activities of third party carriers. The Board also recognizes extenuating circumstances may occur that are beyond a licensee's controls. Licensees should establish policies and procedures to ensure delivery within appropriate temperature requirements given normal and customary delivery times. The Board also recommends establishing a mechanism for patients to contact the pharmacy with delivery concerns.

Policies and procedures should be maintained at the pharmacy or accessible for review on request or during an inspection. A prescription delivery policy/procedure is not required if the pharmacy does not deliver filled prescriptions.

Controlled Substances: Licensees must comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security requirements. Please contact the DEA or BNDD for additional questions.

Prescriptions for Veterinary Use: At the request of a customer, legally filled prescriptions for veterinary use may be delivered to a residence, business, or clinic designated by the customer.

Can pharmacies deliver to drop sites? No. Prescriptions may only be delivered to a site not specified in the rule if the prescription is delivered directly to the patient or the patient's authorized designee.

Prescriptions may be delivered to another pharmacy for dispensing/patient pickup if both pharmacies are in compliance with 20 CSR 2220-2.650 and Class J: Shared Services standards.

E.11 MISBRANDING/ADULTERATION

State and federal law prohibits dispensing any misbranded or adulterated substance. The Board defines "misbranded" and "adulteration" consistent with state and federal law, including, but not limited to, Sections 501 and 502 of the Food, Drug and Cosmetic Act [21 USC § 351, § 352], § 196.095 and § 196.100, RSMo.

Outdated, distressed, misbranded or adulterated drugs must be physically separated from the active inventory and maintained in a separate area. [20 CSR 2220-2.090(2)(V)]. Segregated areas must be adequately marked or identified to ensure outdated, misbranded or adulterated drugs do not re-enter the pharmacy's active inventory.

Reheating/Resealing: The Board has received questions regarding sealing/resealing drugs more than once in the type of packaging where intense heat is utilized to seal the packaging (i.e., blister cards). USP discourages the practice because the effect of reheating on the medication is unknown. As noted by USP, many manufacturers also recommend against heat sealing drugs more than once. In accordance with USP, the Board discourages the practice.

E.12 EARLY FILLS/REFILLS

Board inspectors have observed medications being dispensed too soon to the same patient. In some instances, the "early fills/refills" may result from processing prescriptions from different prescribers or refilling a prescription on a cycle that does not correlate with previously dispensed amounts. Under state and federal law, pharmacists have a professional obligation to ensure drugs are dispensed for bona fide purposes and are not being abused or diverted due to excessive purchases. Licensees should review patient records to ensure compliance with prescribed directions and to prevent excessive dispensing.

E.13 CHILD RESISTANT CONTAINERS

The Board has signed an agreement with the Consumer Product Safety Commission ("CPSC") to assist in enforcing child resistant container laws. All dispensed prescriptions must be packaged in a child resistant container. A non-child resistant container may be issued if:

- The physician specifically requests that a non-child resistant container be dispensed. Pharmacists cannot honor blanket requests from a prescriber to never use safety caps for the prescriber's patients, or;
- The patient specifically requests a non-child resistant container. Patients may issue a blanket request for all prescriptions. However, a request on a single prescription cannot be used as a blanket waiver for subsequent prescriptions. The Board recommends documenting patient requests in writing.

The Board is required to report significant violations of the child resistant container laws to the CPSC. Under federal law, violations may result in criminal or civil liability. The pharmacy related provisions of the Poison Prevention Packaging Act can be found at 16 CFR 1700.14.

E.14 TABLET SPLITTING

A number of insurance plans and their agents require tablet splitting. Generally, pharmacists have been asked to:

- Dispense double the strength of a prescribed drug and then split the tablets in half for the delivery of the original intended dose. After splitting the tablets, the pharmacist makes changes to the directions to coincide with the change in tablet strength, or;
- Supply a drug in whole form and change the label directions to indicate that half of a tablet is to be administered for each dose. Some insurance plans are requiring that tablets with coatings or non-scored tablets be dispensed with the expectation that they be split.

The Board is concerned that these practices may not be in the patient's best interest. As licensed professionals, pharmacists must provide medications in their proper form. Only drug products that are scored should be used in tablet splitting. This includes splitting tablets into half or quarter tablets. Drugs that are not scored will likely not split in a manner that will provide a uniform dose. Coated tablets may also present problems because once the drug is split, any effect the coating provides may be compromised.

Before tablet splitting, pharmacists should verify that:

1) The literature, or other recognized compendia for the drug, recognizes or indicates that splitting of the specific brand of tablet can be accomplished safely and effectively;
2) The prescriber has approved any change in the prescription if a strength higher than that originally prescribed is used. The prescriber must authorize dispensing a higher strength, and;
3) The patient has received detailed patient counseling to ensure the patient understands the changes made. If the patient is responsible for splitting the tablet, counseling should be provided on splitting techniques and the use of any related items (i.e., tablet splitters).

E.15 PREPACKAGING [20 CSR 2220-2.130]

To assist in dispensing, medication may be removed from the original manufacturer's container and placed in a dispensing container/system where the medication will be stored until dispensed to a patient (i.e., an automatic dispensing system). Only products that will be directly provided to the patient may be prepackaged.

Proper sanitation procedures must be utilized when prepackaging drugs. Drugs should not be handled with bare hands. Additionally, containers and equipment must be properly cleaned and maintained to prevent contamination. Reusable containers should be kept clean of tablet dust and other contaminants.

At a minimum, containers used for prepackaging must meet USP Class B container standards. Light sensitive containers must be used, if applicable. A label must be affixed to the prepacked drug container indicating the drug's name and strength, the manufacturer/distributor and the required expiration date. The maximum allowed expiration date is twelve (12) months or the manufacturer's expiration date, whichever is less. In lieu of the required label, licensees that store drugs in an automated counting device may record the required lot number/expiration date in the pharmacy's records, provided the information must be fully traceable and readily retrievable during an inspection.

E.16 PATIENT MED PAKS [20 CSR 2220-2.145]

In lieu of dispensing multiple containers, licensees may dispense multiple medications in a single customized patient medication package ("patient med pak"). Patient med paks must comply with rule 20 CSR 2220-2.145. An authorized

"patient med pak" is defined as a package prepared for a specific patient that consists of one or more containers which contain two (2) or more prescribed drugs. Patient med paks may only be used for solid oral dosage forms (i.e., tablets). Med paks may not contain controlled substances.

Prior to dispensing a med pak, pharmacists must consider:

- Any applicable compendia requirements or guidelines;
- The physical and chemical compatibility of the dosage forms placed in each container; and
- Any therapeutic incompatibilities if the medications are administered simultaneously. *The Board encourages licensees to report any observed or reported incompatibilities to USP.*

Containers: Med Pak containers must be non-reclosable or designed to show if the container has been opened. Containers must comply with the moisture permeation requirements for a Class B single-unit or unit-dose container, unless more stringent requirements exist for a drug contained in the med pak. USP has warned about potential physical and/or chemical incompatibilities when certain drugs are packaged together. Pharmacists must ensure that no interactions will occur when preparing multi-med packages.

Labeling: Med paks must be designed or each container labeled to indicate the day and time or period of time that the contents in each container should be taken. Med paks must also bear a label indicating:

1) The patient's name;
2) A serial number for the patient med pak and a separate serial number for each prescription order for each drug contained in the med pak;
3) The name, strength, physical description or identification and total quantity of each drug product;
4) Directions for use and any cautionary statements contained in the prescription order for each drug;
5) Any storage instructions or cautionary statements required by the official compendia;
6) The name of the prescriber for each drug product;
7) The preparation date and beyond-use date assigned. The beyond-use date may be no later than sixty (60) days from the date of preparation;
8) The name, address, and telephone number of the dispenser; and
9) Any other information, statements, or warnings required for any drug included.

If intact containers can be removed or separated from the patient med pak, each individual container must contain a label that identifies all medication in the container.

Package Inserts: Package inserts/medication guides must be provided if required for any drug in the med pak. In lieu of an individual insert, required information may be incorporated into a single, overall insert for the entire med pak.

Records: In addition to the prescription, records must be maintained for each med pak dispensed. Records must include:

1) The patient's name and address;
2) The prescription serial number for each drug contained in the med pak;
3) The name of the manufacturer/labeler and lot number for each drug;
4) The preparation date and the assigned beyond-use date;
5) Any special labeling instructions;
6) The name or initials of the preparing pharmacist; and
7) Information identifying or describing the design, characteristics, or specifications of the med pak. The med pak must be described in a manner that would allow an identical med pak to be made.

Returns: Generally, med paks that have been delivered to an institution or to a patient cannot be returned to the pharmacy. However, 20 CSR 2220-2.145 provides a pharmacist may modify/repackage a med pak that has been delivered to an institution or patient if:

1) The med pak is returned to the pharmacy that originally dispensed the med pak;

2) The med pak is modified/repackaged, per prescription order, for the same patient to whom it was originally dispensed;
3) The med pak is labeled in compliance with 20 CSR 2220-2.145. The med pak must retain the original beyond use date assigned to the med pak before modification/ repackaging;
4) The med pak is assigned a new serial number, and;
5) The medications removed from the med pak are destroyed in compliance with state and federal law. Removed meds CANNOT be returned to stock or redispensed to either the same or a different patient.

Pharmacists modifying/repackaging medication pursuant to 20 CSR 2220-2.145 must comply with all applicable record keeping requirements.

Except as otherwise allowed by 20 CSR 2220-2.145 for modification/repackaging purposes, medication that has been commingled with other drugs in a med pak may not be returned to stock, dispensed, or distributed except for destruction.

Compliance with 20 CSR 2220-2.145 is required even if the container is supplied by the patient.

E.17 RETURN, REUSE & DISPOSAL

Return To Stock [20 CSR 2220-3.040]: A prescription may be returned to stock if:

1) The patient did not receive the prescription; and
2) The prescription was maintained in the pharmacy's possession in accordance with the manufacturer's labeled storage requirements at all times.

The prescription must be maintained in the original patient container with the name of the drug, dispensing date and the prescription number visible on the container. Notations may be made on the label to distinguish it from active prescriptions being processed.

If returned to stock, the drug's expiration date must become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known. The pharmacy must delete the dispensing in the pharmacy's records and reverse/credit any third party payor claims (i.e., insurance).

Drugs returned to stock may not be poured back into the original stock container because the drug has undergone manipulation outside of its original container. The mixing of lot numbers is also prohibited. Drugs returned to a stock container will be deemed misbranded and/or adulterated in violation of state and federal law.

Errors/Recalls: As authorized by federal law, the Board has allowed returns to the pharmacy if the wrong medication was dispensed to the patient or in instances of a drug recall. In no instance may returned medication be reused or returned to stock. [20 CSR 2220-3.040(3)].

Long-Term Care/Hospice Facilities and Hospitals: See M-5 for authorized returns from a long-term care facility or from a hospital or a hospice facility regulated by the Missouri Department of Health and Senior Services.

Returns for Disposal: The Board has filed a proposed rule to allow pharmacies to accept returned medication from the public for purposes of disposal. The proposed rule will likely be effective in the spring of 2017. In the interim, § 338.315 provides: *"it shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs from anyone other than a licensed or registered drug distributor or pharmacy."* Similarly, 20 CSR 2220-3.040 prohibits a pharmacist/pharmacy from accepting any drug or prescribed medicine, device or product for reuse or resale. As a result, a pharmacy cannot currently accept returns of legend products for disposal

from any person, including, the patient. This restriction also applies to patient med paks that have been dispensed to the patient or an institution.

Licensees should monitor the Board's website for future updates on the pending drug return rule.

Medication Take Back Programs: The Board is aware of alternative drug take-back programs conducted by state and federal law enforcement agencies. Under these programs, drugs are returned to collection sites/ receptacles that are under the supervision of law enforcement personnel and located outside of the permitted pharmacy area. The Board considers these programs to be in compliance with Missouri law if the licensee does not take possession of returned medications for purposes of disposal as prohibited by statute.

The Board will not consider returned medication to be under the possession of a licensee if: (1) medications are returned to collection sites/receptacles that are outside of the permitted pharmacy area(s), (2) returned medications remain under the control of law enforcement at all times, and (3) law enforcement personnel are present whenever drugs are returned or on site. The Board recognizes the important role take-back programs can play in preventing diversion and eliminating environmental hazards. Resources on safe patient disposal are available on the Board's website. To ensure compliance, licensees should review all applicable state and federal law before participating in a take-back program.

E.18 DISTRIBUTING vs. DISPENSING [§ 338.333, § 338.330]

Pharmacies may transfer legend drugs or drug-related devices to another pharmacy or an authorized prescriber by invoice (schedule III-V drugs/non-controlleds) or via a paper/electronic DEA 222 form (schedule II drugs). Prescriptions cannot be used to transfer drugs to a pharmacy or prescriber. A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy's total gross sales. Total gross sales are calculated based on the pharmacy's total annual prescription drug sales, or if prescriptions are not sold, 5% of the pharmacy's total purchases. [§ 338.330(2); 20 CSR 2220-5.050(1)(B)]. *See C.18 for Class-B exemptions.*

If medication is transferred by invoice, the pharmacy's invoice record must include:

- Date of distribution;
- Product name/strength;
- Quantity;
- The names of the parties; and
- The transferring pharmacy's full address and, if a controlled substance, DEA #.

Invoices must be maintained in the pharmacy's records separately from prescription records.

Controlled substance transfers must comply with federal/state controlled substance laws. Pharmacies may not repackage drugs for distribution to other pharmacies or practitioners without being registered with the FDA as a repackager.

Pharmacies that "borrow" or "loan" medication amongst themselves must maintain records of the transactions (invoice/DEA-222). In a borrowing and payback scenario, the pharmacy must have two transaction records: one record documenting receipt of the products and one record documenting the return of the product. The same documentation must be maintained by the pharmacy loaning the product. Intra-store transfers must also be recorded/documented.

E.19 VACUUM TUBE DELIVERY SYSTEMS [20 CSR 2220-2.800]

Vacuum tube systems may be used to deliver medication to a patient if the system is designed and engineered to ensure drug security and to ensure that drugs are correctly and efficiently delivered. The system must be dedicated solely to delivering drugs from within a licensed pharmacy and cannot be used for other departments or combined/attached to any other system (i.e., grocery delivery). The system must be turned off and medication may not be delivered if the pharmacy is closed or when there is no pharmacist on duty.

Vacuum tube systems must allow pharmacy personnel and the consumer to communicate effectively both orally and in writing. Pharmacies using a vacuum tube system must maintain a direct and identifiable line of sight with the consumer. Alternatively, a video camera and audio system may be used to identify consumers. The video monitor/audio system must be in good working order or use must be discontinued until corrections/repairs are made. At a minimum, video monitors must be at least twelve inches (12") wide. The pharmacy must consider backlighting or other factors that may inhibit video/audio performance.

The patient's identification must be verified before drugs are delivered. To prevent confusion, the Board recommends using multiple identifiers (i.e., birth date, address). *[See 20 CSR 2220-2.800(2) for vacuum systems installed before September 1, 1988].*

E.20 AUTOMATED FILLING SYSTEMS [20 CSR 2220-2.950]

Rule 20 CSR 2220-2.950 establishes requirements for pharmacists using an automated filling system (AFS) to dispense prescriptions. An AFS is defined as "*an automated system used by a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling or sealing medication for dispensing"*. An AFS does not include: (1) automated devices used solely to count medication (counting devices), (2) vacuum tube drug delivery systems governed by 20 CSR 2220-2.800 or (3) automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to a patient.

A pharmacist must inspect and verify the contents and label of every prescription filled by an AFS unless:

- A pharmacist verifies the accuracy of the prescription data used by or entered into the AFS for the specific patient prior to filling. The identity of the verifying pharmacist must be documented in the pharmacy's records and maintained for five years [20 CSR 2220-2.950(4)(C)]; and
- A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was loaded in the AFS before initiating the fill process. [20 CSR 2220-2.950(4)(D)]. An electronic verification system may be used to verify manufacturer unit of use packages or repacked medication previously verified by a pharmacist.* *Repacked containers must comply with 20 CSR 2220-2.130; and*
- The filling process is fully automated from the time the process is initiated until a completed prescription is produced that is ready for dispensing to the patient. [20 CSR 2220-2.950(4)(B)]. In other words, AFS must fill, label, and seal the prescription in the container or the prescription must be dispensed by the AFS in a manufacturer's unit of use package or a repacked pharmacy container. [20 CSR 2220-2.950(4)(E)]. *No manual intervention with the medication or prescription may occur after the medication is loaded into the AFS.* Pharmacy staff may prepare or package the final labeled product container for mailing, storage or delivery. However, no other manual intervention is allowed; and
- An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient [20 CSR 2220-2.950(4)(F)] ; and;*
- Daily random quality testing is conducted by a pharmacist on at least two percent (2%) of the prescriptions filled by the AFS on the date tested or filled by the AFS on the last day of system operation. The pharmacist-in-charge must determine how the sample is selected. Proof of compliance, random quality testing date(s) and testing results

must be documented and maintained in the pharmacy's records and available for inspection. [20 CSR 2220-2.950(4)(G)]

** Electronic verification systems must comply with 20 CSR 2220-2.950(1)(B). Video/camera verification systems alone do not qualify as electronic verification systems.*

Significantly, pharmacies using an AFS in lieu of physical pharmacist verification must test the system before initial use, when restarting the system or after any modification to the AFS or electronic verification system has been made that may change or alter the filling/electronic verification process.

Pharmacies using an AFS in lieu of physical product inspection/verification by a pharmacist must maintain written policies and procedures to monitor and ensure the AFS is functioning properly and safely. 20 CSR 2220-2.950(5) contains a detailed listing of minimum policy/procedure requirements. Policies/procedures must address:

- System maintenance
- Accurate loading
- Sanitation, cross-contamination
- Expired/recall drugs
- Errors and malfunctions
- Testing
- Training
- System Access
- Tracking responsible persons
- Quality Assurance

AFS policies and procedures must be reviewed annually and maintained in the pharmacy's records for at least two (2) years.

The required AFS policies and procedures and mandatory testing only apply if a pharmacist is not physically inspecting and verifying the final product. Pharmacies physically verifying the final contents and label of medication filled or packaged by an AFS are not subject to the additional requirements of 20 CSR 2220-2.950(4) – (6).

E.21 EMERGENCY PHARMACIST DISPENSING [§ 338.200]

Section § 338.200, RSMo, authorizes a Missouri pharmacist to dispense an emergency supply of medication if the pharmacist is unable to obtain refill authorization from the prescriber. Pharmacists may dispense an emergency supply if:

- In the pharmacist's professional judgment, interruption of therapy might reasonably produce undesirable consequences;
- The pharmacy previously dispensed or refilled a prescription from the prescriber for the same patient and medication;
- The pharmacist informs the patient or the patient's agent at the time of dispensing that prescriber authorization is required for future refills. Notification can be made verbally, electronically or in writing, and;
- The emergency dispensing is documented in the patient's prescription record.

The emergency supply must be limited to the amount needed for the emergency period as determined by the pharmacist within his or her professional judgment. However, the total amount dispensed shall not exceed a seven-day supply. If the prescriber is deceased, incapacitated or unable to provide medical services, up to a thirty-day supply may be dispensed.

The Board recognizes that some medications are dispensed in manufacturer packaging that exceeds a seven day supply. However, § 338.200.2 provides the amount dispensed shall "not exceed a seven day supply" if the prescriber is not deceased or otherwise incapacitated. The Board recommends that pharmacists consult with legal counsel and use their professional judgment as needed for the emergency period in such circumstances.

E.22 NALOXONE DISPENSING

In 2016, HB 1568 was passed which authorizes Missouri licensed pharmacists to sell and dispense an "emergency opioid antagonist" without a prescription under protocol with an authorizing physician. An "emergency opioid antagonist" is defined as:

> *Naloxone hydrochloride that blocks the effects of an opioid overdose that is administered in a manner approved by the United States Food and Drug Administration or any accepted medical practice method of administering. [§ 195.206, RSMo]*

No additional Board license or certification is required for dispensing pharmacists.

HB 1568 allows any individual or entity to purchase naloxone and does not include dispensing limits or quantity restrictions. However, the pharmacist's protocol may include additional restrictions.

Once again, pharmacists must have a naloxone dispensing protocol with a licensed physician. The Board anticipates reviewing applicable protocol standards in the future. In the interim, the Board suggests that naloxone protocols include provisions/requirements for:

- Pharmacist education and training
- Emergency notification and documentation
- Patient education and counseling, and
- Protocol review, signatures and timeframe.

A sample protocol template is available on the Board's website. Licensees should maintain proof of the authorizing physician's licensure in the pharmacy's records.

All naloxone sales/dispensing must be documented. If dispensing naloxone by prescription, licensees must comply with all prescription recordkeeping requirements. If sold by protocol, the pharmacy must have a record of the sale that should include:

- Transaction date
- Product name, strength and dosage form; and
- Quantity; and
- The names of the parties/entities (if known)

Pharmacists should educate themselves before dispensing or administering naloxone. To assist licensees, the Board has established a Naloxone Resource page on its website that contains a variety of free state and federal naloxone resources for pharmacists.

The Board also recommends that pharmacists educate patients on the proper use and administration of naloxone whenever possible. The Board has drafted a free patient educational brochure titled: "Opioid Safety and Naloxone: A Guide for Missouri Patients and Caregivers" which is available on the Board's website. Complimentary copies of the brochure can also be requested by e-mailing MissouriBOP@pr.mo.gov or by contacting the Board office.

First Responder Agencies: Section 190.255 authorizes any licensed drug distributor or pharmacy to sell naloxone to a "qualified first responder agency". A "qualified first responder agency" is defined as "any state or local law enforcement agency, fire department or ambulance service that provides documented training to its staff related to the administration of naloxone in an apparent narcotic or opiate overdose situation." A protocol is not required to provide naloxone to a qualifying first responder agency.

Naloxone sales to a qualified first responder agency should be documented by invoice. Prescriptions cannot be used to document the sale. Invoices should include:

a) The date of sale;
b) Product name;
c) Quantity Sold;
d) The identity of the qualified first responder agency; and
e) The transferring pharmacy's full address.

Invoices must be maintained in the pharmacy's/distributor's records and filed separately from prescription records.

E.23 EPINEPHRINE/ASTHMA MEDICATION

Section 167.630, RSMo, authorizes Missouri school districts to obtain prefilled epinephrine auto syringes by prescription. Section 167.635 contains the same allowance for asthma related rescue medications. To obtain prefilled epinephrine auto syringes or asthma related rescue medications, a prescription is required from a licensed physician, a physician's assistant, or nurse practitioner. The school district must be designated as the patient and the school nurse's name must be on the prescription. Pharmacies may legally dispense prescriptions that comply with § 167.630 or § 167.635.

F.1 GENERAL REQUIREMENTS

A Class D (Non-Sterile Compounding) pharmacy permit is required for pharmacies performing non-sterile compounding in batch quantities using bulk active ingredients. Rule [20 CSR 2220-2.400] defines compounding as:

> *The preparation, incorporation, mixing and packaging or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding also includes the preparation, incorporation, mixing and packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.*

The Board does not consider reconstituting or mixing ingredients for an FDA approved non-sterile drug product to be compounding (i.e., Benzaclin, Benzamycin, Epaned etc.). However, the use of compounding kits that include the compounding ingredients is considered compounding (i.e., CutisPharma First Kits). Licensees using compounding kits that include the compounding ingredients must comply with the Board's compounding rules, including, completion of the compounding log.

Pharmacies may not compound products that have been withdrawn from the market due to safety.

As defined by the Board's rules, compounding does not include incorporating a flavoring agent. However, licensees should indicate that the product was flavored on the patient container and the added flavoring must be documented in the prescription record. Licensees may not flavor a prescription dispensed by another pharmacy. Flavoring an OTC product requires a prescription.

F.2 PRESCRIPTION REQUIREMENTS

Except as otherwise provided by law, pharmacists/pharmacies may only dispense compounded products pursuant to a prescription (or a medication order for Class-B pharmacies). Pharmacists/pharmacies may not offer compounded products to other pharmacies, practitioners or commercial entities for office use or for subsequent resale. [20 CSR 2220-2.400(12)] Pharmacies/pharmacists may, however, dispense a compounded product for a prescriber to administer in his office if a valid prescription or medication order has been received for the individual patient.

Pharmacists/pharmacies may compound drugs in "limited quantities" prior to receiving a valid prescription if there is a history of receiving/filling valid prescriptions pursuant to an established relationship between the pharmacist, patient and prescriber. [20 CSR 2220-2.400(7)(C)]. For purposes of 20 CSR 2220-2.400, a "limited quantity" is defined as a three (3) month supply of a batched product or a one (1) year supply for compounded products intended for external use (i.e., creams, ointments, lotions or liniments). While advance preparation is allowed, a prescription is required for dispensing.

Compounding may only be done by prescription/medication order, regardless of the type of product (i.e., OTC, herbal). [20 CSR 2220-2.400(10)].

Pharmacies/pharmacists are prohibited from compounding for office stock unless the pharmacy is licensed as a Missouri drug distributor and is registered with the FDA as a drug manufacturer or a 503(b) drug outsourcing facility.

F.3 COMMERCIALLY AVAILABLE PRODUCTS

Pharmacists may not compound products that are commercially available or that are essentially copies of commercially

available products. [20 CSR 2220-2.400(9)]. "Essentially copies" include different dosage forms (i.e., suspension vs. solution, tablet vs. capsule). Missouri law recognizes the following exemptions:

- A commercially available product may be compounded if the product is temporarily unavailable due to problems other than safety or effectiveness (i.e., shortage, a back order). Licensees should document unavailability in the prescription record. [20 CSR 2220-2.400(9)]. The Board recommends documenting the dates the product was unavailable and keeping any documentation from the manufacturer/distributor. Licensees must stop compounding the product once the commercially available product returns to the market.
- A commercially available product may be compounded if there is sufficient documentation of a specific medical need for the prescription/medication order. [20 CSR 2220-2.400(9)]. The "specific medical need" is the medical reason why the commercially available product cannot be used. Cost or convenience are insufficient reasons.

"Sufficient documentation" is considered to be either a prescription or medication order documenting the specific medical need or a notation in the pharmacy's records that verbal or other documentation of the medical need was received for each prescription/medication order. Notations should include the name of the person verifying the medical need, the date, and the specific medical need/reason given.

The Board does not consider compounding kits that include compounding ingredients to be commercially-available so a pharmacy may still compound these preparations without using the kit.

F.4 PRODUCT VERIFICATION

The dispensing pharmacist must ensure that compounded products have been properly prepared, labeled, stored, dispensed and distributed. [20 CSR 2220-2.400(8)] Before release, the pharmacist must visually inspect bulk drug substances and all finished products for container closure integrity, visible particulates or other foreign matter/visual defects.

For quality purposes, the dispensing pharmacist must also ensure that:

1) Each person assisting in compounding is capable and qualified to perform their assigned duties;
2) All ingredients have their expected identity, quality and purity;
3) Reasonable assurance exists that compounding processes/procedures are always carried out by pharmacy staff as intended or specified; and
4) Compounding conditions/procedures are adequate for preventing mix-ups or other errors.

The Board has observed several instances of pharmacists compounding with expired ingredients. In many instances, the expired date was recorded in the compounding log signed by the pharmacist. Pharmacists should review all log entries for accuracy. Additionally, proactive steps should be taken to identify and remove expired drugs and ingredients.

F.5 LABELING

In addition to other prescription labeling requirements, the actual name of each active or therapeutic ingredient contained in a compound must be listed on the patient's prescription container or on an auxiliary label (i.e., labels that indicate only "magic mouthwash" are non-compliant.) [20 CSR 2220-2.400(7)(F)].

F.6 BEYOND-USE DATES

Batched compounded products must be assigned an in-house batch/lot number and a "beyond-use date" after which a compounded preparation should not be used. [20 CSR 2220-2.400(7)(A)6.] The beyond-use date must be determined from the date the preparation is compounded. Licensees should use their professional judgment in determining appropriate beyond-use dates. Because compounded products are intended for immediate administration or following short-term storage, beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products. [20 CSR 2220-2.400(4)]. Licensees may be asked to explain or support their rationale for assigning a beyond-use date.

Compounds that are not picked up by the patient and returned to stock are considered batched and must be assigned a batch number and a beyond-use date in the compound log and on the label.

F.7 INGREDIENTS/CONTAINERS [20 CSR 2220-2.400(6)]

Proper controls must be maintained over drug products/ingredients, containers and container closures to prevent contamination. Drug components must meet compendial standards (i.e., USP, NF). If non-compendial bulk drug substances are used, a certificate of analysis must be maintained on file. [20 CSR 2220-2.400(8)2.] Non-drug substances must be contaminant free and maintain full potency.

Container systems must be stored and used in a manner that will adequately protect against foreseeable deterioration or contamination. Drug products, ingredients, containers and container closures may not be reactive, additive or absorptive in any way that would alter the safety, identity, strength, quality or purity of the compounded product beyond the desired result.

Compounding materials must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration. Excess products must be labeled with the name of the drug(s), an in-house lot number and the beyond-use date and must be stored and accounted for under conditions dictated by their composition and stability. [20 CSR 2220-2.400(6)].

For bulk ingredients that do not bear an expiration date, the pharmacy is encouraged to contact the manufacturer to determine the actual expiration date. If one is not provided, the pharmacy is encouraged to have a procedure for establishing an in-house expiration date for the ingredient.

F.8 FACILITIES/EQUIPMENTS [20 CSR 2220-2.400(5)]

Compounding area(s) must be clean and sanitarily maintained at all times. Compounding areas must be free of infestation and trash must be disposed of in a timely manner.

Compounding equipment must be adequately and appropriately designed for the activities performed. Equipment surfaces may not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired. [20 CSR 2220-2.400(6)(E)]. Equipment must be appropriately located to allow for proper use, cleaning and maintenance. [20 CSR 2220-2.400(5)(C)].

If drugs with special contamination precautions are used (i.e., penicillin), appropriate measures must be utilized to prevent cross-contamination. [20 CSR 2220-2.400(5)(B)]. Appropriate measures may include, but may not be limited to, dedicating or adequately cleaning equipment.

F.9 QUALITY CONTROL

Pharmacies must establish and maintain appropriate quality control measures over compounding methods. [20 CSR 2220-2.400(7)] Quality control measures must include:

1) Methods for compounding to ensure finished products have the identity, strength, quality and purity they purport or are represented to possess, and;
2) A description of the compounding process and the order for adding drug products/ingredients, if applicable.

Additionally, pharmacies must develop and maintain an outcome related drug monitoring system for evaluating the quality of compounding services. At a minimum, the monitoring system must evaluate/track infection rates, adverse drug reactions, recalls and prescriber/client complaints.

F.10 COMPOUNDING LOG

Pharmacies must maintain a separate compounding log that includes [20 CSR 2220-2.400(7)(A)]:

1) The compounding method used;*
2) The compounding date;
3) Identity of the compounding pharmacist;
4) A listing of the drug products/ingredients and their amounts by weight or volume;
5) Description of the compounding process and, if necessary for proper compounding, the order of drug product/ingredient addition (i.e., recipe/formula cards);*
6) The source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and
7) A prescription number or a readily retrievable unique identifier for the compound.

** This information may be stored separately in the pharmacy's records, provided the records are immediately retrievable.*

F.11 RECALLS

A recall must be initiated if a compounded product is deemed to be misbranded or adulterated. [20 CSR 2220-2.400(8)(C)]. In the event of a recall, the pharmacy must notify the prescriber of: 1) the nature of the recall, 2) the problem(s) identified and 3) any recommended action(s). If the compounded product could potentially cause patient harm, the same recall notification must be provided to the patient. Recall(s) must be reported to the Board in writing within three (3) business days.

Prescribers may be notified verbally or in writing. Licensees should exercise their professional judgment when determining notification methods. The Board recommends retaining proof of the date and manner of the recall/notification in the pharmacy's records.

F.12 ADVERTISING/SOLICITATION

Licensees may advertise or provide information regarding the availability of compounding services and the type of compounding offered. However, licensees may not compare compounded products to commercially available products or make specific claims without supporting data (i.e., designating a product as slow release). [20 CSR 2220-2.400(12)]. Alternatively, licensees may not attempt to solicit business by making specific claims about compounded products without analytical data to support the claims for each product. Licensees must produce data for their specific product and may not rely on data obtained from other sources.

G.1 STERILE COMPOUNDING

Class H Sterile Compounding pharmacies are required to comply with all applicable provisions of state/federal law, including rule 20 CSR 2220-2.200 governing sterile pharmaceuticals and 20 CSR 2220-2.400 which establishes standards of practice for all compounding pharmacies. See Section F. Compliance with 20 CSR 2220-2.200 and 20 CSR 2220-2.400 is mandatory for all pharmacies holding a Class H Sterile Compounding pharmacy permit even if the pharmacy is not currently providing sterile compounding services.

The Board has not adopted USP Chapter 797 at this time. USP Chapter 797 is currently under revision; the Board intends on reviewing Missouri's regulations after USP Chapter 797 is finalized. Interested parties should monitor the Board's website for additional information.

In August 2016, the Board issued an emergency sterile compounding that substantially revised its sterile compounding rule. Interested parties should review the Sterile Compounding Rule Implementation Guide for additional compliance information. The following major changes were included in the emergency sterile compounding rule and are summarized in the Implementation Guide:

- Compounding definitions (equipment and classified areas)
- Risk-level classifications
- Garbing requirements
- Training requirements
- Cleaning & disinfection requirements
- Media-fill testing
- Environmental monitoring
- End-preparation testing
- Remedial investigations/recalls

G.2 COMPOUNDING RISK LEVELS

Rule 20 CSR 2220-2.200 establishes the following compounding risk levels:

Risk Level	Emergency & Amended Rule
Risk Level 1	• Preparations stored at controlled room temperature and assigned a beyond-use date of 48 hours or less • Preparations stored under refrigeration and assigned a beyond-use date of 7 days or less • Preps stored frozen and assigned a beyond-use date of 30 days or less
Risk Level 2	• Preparations stored at controlled room temperature and assigned a beyond-use date greater than 48 hours • Preparations stored under refrigeration and assigned a beyond-use date greater than 7 days • Preparations stored frozen and assigned a beyond-use greater than 30 days
Risk Level 3	• Products compounded from nonsterile ingredients or compounding with nonsterile components, containers or equipment before terminal sterilization • Products prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

G.3 PRESCRIPTION REQUIREMENTS

As with non-sterile compounding, pharmacies may only dispense compounded sterile preparations pursuant to a patient specific prescription or lawful medication order. [20 CSR 2220-2.400]. Drugs may be compounded in "limited quantities" prior to receiving a valid prescription if there is a history of receiving/filling valid prescriptions pursuant to an established relationship between the pharmacist, patient and prescriber. [20 CSR 2220-2.400(7)(C)]. While products may be prepared in advance, a patient-specific prescription/medication order is required prior to dispensing.

For purposes of 20 CSR 2220-2.400, a "limited quantity" is defined as a three (3) month supply of a batched product or a one (1) year supply for compounded preparations intended for external use (i.e. creams, ointments, lotions or liniments).

G.4 COMPOUNDING FOR OFFICE USE

Pharmacies may not sell or dispense sterile compounds to practitioners or other prescribers for office use. [20 CSR 2220-2.400(1), (12)]. This includes hospitals, surgery centers, etc. Once again, a patient specific prescription/medication order is required prior to dispensing. Pharmacies/pharmacists may only compound for office use if the pharmacy/pharmacist is registered as an FDA drug manufacturer or a drug outsourcing facility.

In 2013, the federal Drug Quality and Security Act (DQSA) was enacted which recognized and established requirements for "drug outsourcing facilities" and references compounding for office use. FDA registered drug outsourcers/manufacturers must also be licensed with the Board as a drug distributor.

G.5 COMMERCIALLY AVAILABLE PRODUCTS

Generally, Missouri law prohibits licensees from compounding preparations that are commercially available or that are essentially copies of commercially available products. "Essentially copies" includes different dosage forms (i.e., suspension vs. solution, tablet vs. capsule).

Licensees may only compound a commercially available product:

- If the product is temporarily unavailable due to problems other than safety or effectiveness (i.e., on back order). Unavailability must be documented in the pharmacy's records. [20 CSR 2220-2.400(9)]. The pharmacy must stop compounding the product once the product becomes available again;
- If a "specific medical need" for the prescription exists. [20 CSR 2220-2.400(9)]. The "specific medical need" is deemed to be the medical reason why the commercially available product cannot be used. The nature of the "specific medical need" must be documented on the prescription or otherwise in the pharmacy's prescription records. [20 CSR 2220-2.400(9)]. Cost or convenience are insufficient to establish a "specific medical need."

G.6 POLICIES & PROCEDURES

Pursuant to 20 CSR 2220-2.200(2), Class H Sterile Compounding pharmacies must maintain a policy and procedure manual that addresses all aspects of sterile compounding performed by the pharmacy. Policy & procedure manuals should be regularly reviewed and updated to ensure appropriate practices. At a minimum, manuals must be reviewed annually. [20 CSR 2220-2.200(2)]. Policy and procedure manuals and documentation of the annual review will be required during inspection.

Board inspectors continue to observe instances of incomplete or outdated policy and procedure manuals. In other cases, pharmacy staff have not been updated or trained on recent policy/procedure changes. Manuals should be accessible to and reviewed by all pharmacy staff, including, new hires. The Board recommends retraining staff when substantive changes or modifications are made or when there is a breach in aseptic technique.

G.7 ADDITIONAL COMPLIANCE REQUIREMENTS

This section includes a general summary of selected rule provisions. Once again, licensees should review the Implementation Guide and rule 2 CSR 2220-2.200 in its entirety for full compliance information. Additional sterile compounding requirements exist that are not listed above, including, but not limited to, PEC/environmental certification, aseptic skills technique training/assessment, media-fill testing, environmental monitoring, recalls and remedial investigations).

H.1 GENERAL REQUIREMENTS

Pharmacies are required to designate a primary record keeping system that may either be a non-electronic (manual) system or an electronic system. [20 CSR 2220-2.010(2)]. All dispensing activities must be recorded in the designated system.

H.2 NON-ELECTRONIC (MANUAL) PRESCRIPTION RECORD SYSTEM

If a non-electronic record system is used, the pharmacy must maintain the following:

- A separate prescription file for Schedule I and II controlled substance prescriptions;
- A separate prescription file for Schedule III, IV and V controlled substance prescriptions; and
- A separate file for all other non-controlled drug prescriptions. [20 CSR 2220-2.010(3)-(4)]

The following information must be maintained in a non-electronic system for each original and refilled prescription:

- The date the prescription was prescribed and the date of initial dispensing, if different;
- A sequential prescription label number or other unique identifier;
- The name of the patient(s), or if an animal, species and owner's name;
- The prescriber's name for oral prescriptions or signature for written or faxed prescriptions. *Electronic signatures must comply with all applicable provisions of 20 CSR 2220-2.085;*
- For controlleds, the address of the prescriber and the patient and the prescriber's DEA number;
- Name, strength and dosage of drug, device or poison dispensed and the directions for use;
- The number of refills authorized;
- The quantity dispensed in weight, volume, or number of units;
- The date of refill, if any;
- The identity of the pharmacist responsible for reviewing the accuracy of data on each original prescription;
- The identity of the pharmacist responsible for verifying the final product prior to dispensing on each original and refill prescription, if different;
- Whether generic substitution has been authorized by the prescriber;
- Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug, and;
- If additional refills are authorized and added to the prescription, a notation indicating the method and source of the authorization must be a part of the manual record or hard copy. The expiration date of the original prescription must remain the same

The identity of the pharmacist verifying prescription data and the pharmacist verifying the final product must be recorded, if different.

Pharmacies maintaining a non-electronic (manual) system must also record the following on the reverse side of the prescription for each refill:

- The date the drug, medicine or poison was dispensed;
- The dispensing pharmacist's initials; and
- The amount of drug dispensed to the patient, if different from the face of the prescription. [20 CSR 2220-2.010(3)]

Prescriptions must be filed by the prescription number/unique identifier. [20 CSR 2220-2.010(2); 20 CSR 2220-2.017].

H.3 ELECTRONIC PRESCRIPTION RECORD SYSTEMS [20 CSR 2220-2.080]

If an electronic prescription record is designated, the system must allow for the separate identification/ retrieval of Schedule I and II controlled substance prescriptions, the separate identification/retrieval of Schedule III-V controlled substance prescriptions and the separate identification/retrieval of other non-controlled prescriptions. Required prescription hard copies must be stored in a three-file system as listed in section H.2.

Electronic record systems must be able to store and retrieve the following for each original and refill prescription:

1) A unique, sequential prescription label number;
2) If applicable, a unique readily retrievable identifier;
3) Date the prescription was prescribed;
4) The date the prescription was initially filled and the date of each refill;
5) Patient's full name, or if an animal, the species and owner's name;
6) The patient's address or animal owner's address, if a controlled substance has been prescribed;
7) The prescriber's full name.
8) For controlled substances, the prescribers address and DEA #;
9) Name, strength and dosage of drug, device or poison dispensed and any directions for use;
10) Quantity originally dispensed;
11) Quantity dispensed on each refill;
12) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
13) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;
14) The number of authorized refills and quantity remaining;
15) Whether generic substitution has been authorized by the prescriber;
16) The manner in which the prescription was received by the pharmacy (i.e., written, telephone, electronic, or faxed); and
17) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or substitution authority. If additional refills are authorized, the EDP system must indicate the method and source of authorization. [20 CSR 2220-2.080(2)]

Information may be entered into the EDP system by a licensed pharmacist or a pharmacy technician or intern pharmacist working under the pharmacist's direct supervision. [20 CSR 2220-2.080(1)]. However, the pharmacist is personally responsible for the accuracy of information inputted. [20 CSR 2220-2.080(1)].

Production of Records: An EDP system must be capable of retrieving records within two (2) hours of a request by a Board inspector. Alternatively, the pharmacy must provide a computer terminal that will allow the inspector to immediately access the system. An inspector may ask for code/login information to access records [20 CSR 2220-2.080(7)].

Drug Utilization: EDP systems must be able to retrieve a drug utilization listing for any drug for the previous twenty-four (24) months. Information must be available by specific drug product, patient name or practitioner. Drug utilization reports must be provided within three (3) working days of a Board request. [20 CSR 2220-2.080(12)].

In 2013, the Board removed the requirement that a pharmacist maintain a bound logbook or separate file (a.k.a. the "pharmacist signature log") signed daily by the pharmacist to verify that prescription information was accurately entered. Instead, the pharmacy's electronic prescription record must now identify the pharmacist responsible for verifying the accuracy of prescription data on each original prescription. Federal law still requires licensees to maintain a logbook or a signed printout for verifying controlled substance refill data. [See 21 CFR 1306.22(f)(3)]

H.4 PRESCRIPTION HARD COPIES

Section 338.100, RSMo, requires that the "original or order" of each drug must be maintained by the pharmacy for at least five (5) years. Accordingly, a hard copy of each prescription must be maintained by the pharmacy regardless of source (faxed or electronic). For prescriptions received electronically, a hard copy of the prescription must be printed and maintained in the pharmacy's records unless the pharmacy has an electronic record-keeping system as described in Section H. Prescriptions must be filed by the consecutive number or the unique identifier. Note: The hard copy requirements also apply to controlled substances. A hard copy of an electronically prescribed controlled substance must be printed unless the pharmacy has an electronic record-keeping system that maintains a digital image of what was received.

H.5 ELECTRONIC RECORD KEEPING SYSTEMS (ERS)

In lieu of a prescription hard copy, pharmacies that have an electronic record keeping system that complies with § 338.100, RSMo, may maintain a digitized image of a prescription. Rule 20 CSR 2220-2.083 defines an electronic record keeping system, or "ERS", as a system that provides "input, storage, processing, communications, output and control functions for digitized images of original prescriptions."

An electronic prescription record is different from an electronic record keeping system. To qualify as an ERS, the pharmacy's system must be able to capture "an exact digitized image" of the actual prescription, including, the reverse side of the prescription, if applicable. Simply transferring or electronically recording prescription data is insufficient. Pharmacies that do not have a compliant ERS must still maintain a prescription hard copy.

Digitized prescription images in an ERS must be readily retrievable and capable of being provided or reviewed immediately or within (2) hours of a request from the Board or a Board inspector. To prevent loss, digitized images in the ERS must be stored, copied or saved onto secure storage media on a regular basis. Pharmacies with an ERS must maintain a written policy and procedure manual that includes policies/procedures for reviewing compliance.

H.6 CONFIDENTIALITY

Patient records must be confidentially maintained in compliance with HIPAA and all state and federal law. Licensees have a duty to properly safeguard confidential records. The Board is aware that records may be reviewed by third-party entities conducting audit/review functions (i.e., pharmacy benefit managers, private consultants). Confidential records that do not relate to a third-party inquiry must be securely maintained to avoid unauthorized access/disclosure.

Pharmacies should exercise caution in discarding or destroying drug containers. Patient specific information should be removed before placing the container in the trash or giving the container to a reverse distributor.

H.7 RECORD RETENTION

(This chart includes select record keeping requirements and is not a complete listing. Licensees should review all relevant laws to ensure record keeping compliance.)

PHARMACIST		
Continuing Education	Must be retained for two (2) reporting periods immediately prior to renewal	20 CSR 2220-7.080
PHARMACY		
Audit of Class-I Consultant Pharmacy Records	3 Years	20 CSR 2220-2.010(10)(A)3.
Compounding Log	2 Years	20 CSR 2220-2.400(7)(E)
Compounding Records	2 Years	20 CSR 2220-2.400(7)(E)
Controlled Substance Prescription Orders	5 years	§ 338.100, RSMo
Controlled Substance Transfer Records/DEA 222 forms	2 Years	21 CFR 1304.04
Controlled Substance Inventories	2 Years	§ 195.060, RSMo
Distribution Records	2 Years	20 CSR 2220-2.010(5)
Drug Invoices	2 Years	20 CSR 2220-2.010(5)
Immunization/Medication Administration Records	2-Years	20 CSR 2220-6.050(6)(D)2. 20 CSR 2220-6.040(6)(B)
Immunization Protocol	8 Years after termination	20 CSR 2220-6.050(5)(B)
Medication Therapy Services (MTS) Protocol	7 Years	20 CSR 2220-6.080(7)(B)
MTS Patient Records (generally)	7 Years	20 CSR 2220-6.080(7)
Prescription Orders	5 Years	§ 338.100, RSMo
Sterile Compounding Records	2 Years	20 CSR 2220-2.200(9)(A)

I.1 GENERAL REQUIREMENTS

Section 338.010, RSMo, authorizes a pharmacist to administer the following vaccines pursuant to a written protocol with a Missouri licensed physician: influenza, shingles, meningitis, pneumonia, hepatitis A, hepatitis B, tetanus, diphtheria and pertussis. Patients must be at least 12 years old.

Prior to immunizing, pharmacists must file a Notification of Intent with the Board and meet all qualification requirements (see 20 CSR 2220-6.050). Vaccinations may only be delegated to qualified intern pharmacists as described below.

Licensees immunizing by protocol must comply with:

- All state and federal laws governing vaccine information statements and informed consent;
- Manufacturer guidelines, and;
- All applicable Centers for Disease Control (CDC) guidelines. Compliance with CDC guidelines is mandatory even if manufacturer recommendations are different.

After immunizing, patients must be asked to remain in the pharmacy a "safe amount of time" to observe any adverse reactions. [§ 338.010.12(2)]. The term "safe amount of time" is not defined in statute. Pending further rulemaking, pharmacists should use their professional discretion when determining the time needed to adequately assess adverse reactions. The Board recommends documenting when a patient refuses to stay.

See section E.22 for dispensing naloxone by protocol.

I.2 IMMUNIZATION QUALIFICATIONS

Section 338.010, RSMo, and 20 CSR 2220-6.050 establishes the following requirements for pharmacists immunizing by protocol:

	Immunization By Protocol Requirements
Authorized Vaccines	• Influenza, shingles, meningitis, pneumonia, hepatitis A, hepatitis B, tetanus, diphtheria & pertussis. *This includes combination products with the authorized vaccines (i.e., Tdap).* • Patient must be at least 12 years old
Qualifications	• Active Missouri RPh license • Notification of Intent filed with Board *(must be filed online)* • Current CPR certification from the American Heart Association, American Red Cross or an equivalent body • Completion of vaccine administration certificate program accredited by ACPE or an entity approved by the Board • Protocol with a Missouri licensed physician
Notification Renewal	• Notification of Intent filed annually with the Board *(must be filed online)* • Current CPR certification • Two (2) CE hours (0.2 CEU) related to administration of vaccinations within the prior twelve (12) months

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Missouri Licensed Intern Pharmacists	May immunize if the intern: • Has a current and active CPR certification • Has completed an immunization certificate program accredited by ACPE or an entity approved by the Board • Is under the direct supervision of a pharmacist qualified to immunize

Section 338.100.12 requires that pharmacists administering vaccines display a certificate showing that he/she has met all immunization training requirements. The Board does not issue a separate immunization certificate/license. Instead, licensees should print and display their online license verification from the Board's website which will show if a Notification of Intent has been filed. Online license verifications can be retrieved online by the licensee's name at https://renew.pr.mo.gov/pharmacy-licensee-search.asp. Posting an immunization training certificate does not meet the statutory requirement.

I.3 PROTOCOL REQUIREMENTS

To immunize, pharmacists must have a written protocol with a Missouri-licensed physician who is actively engaged in the practice of medicine. [20 CSR 2220-6.050(6)]. The authorizing physician's practice location must be no further than fifty (50) miles by road from the pharmacist, using the most direct route available. The protocol may be valid for no longer than one (1) year from the date signed and must include:

1. *The identity and signature of the participating pharmacist and physician;*
2. *The time period of the protocol;*
3. *The vaccines which may be administered;*
4. *The identity of the patient or groups of patients who may be vaccinated;*
5. *The authorized routes and anatomic sites of administration;*
6. *Provisions for creating a prescription for each administration under the authorizing physician's name;*
7. *A course of action for addressing emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;*
8. *The length of time the pharmacist is required to observe a patient for adverse events following an injection;*
9. *Provisions for disposing of used and contaminated supplies;*
10. *The street addresses of the pharmacy or other locations where vaccines may be administered;*
11. *Record keeping requirements and procedures for notification of administration; and*
12. *Provisions for terminating the protocol at the request of any party at any time.*

A new protocol must be signed each year. Protocols must be maintained for at least eight (8) years after the protocol is terminated.

Protocol Amendments: Amendments to the protocol must be signed and dated by all participating pharmacists and prescribers. Signatures may be included on the original protocol or on a separate document that is attached to the protocol. Pharmacists may be added to an existing protocol if the protocol is signed by both the newly added pharmacist and the authorizing physician(s).

The Board has observed multiple instances where the protocol did not include each location where a pharmacist immunizes as a relief or "floater" pharmacist. Licensees should check their protocols to make sure each immunization location is listed before immunizing.

I.4 PRESCRIPTION REQUIREMENTS

Within seventy-two hours (72) hours after administering a vaccine by protocol, the pharmacist must either obtain a prescription from the authorizing physician for the vaccine or create a prescription under the protocol physician's name documenting the dispensing. [20 CSR 2220-6.050(7)(B)]. A prescription may only be created if authorized by the governing protocol. The protocol physician must be listed as the prescriber and not the pharmacist/intern pharmacist.

I.5 NOTIFICATION REQUIREMENTS

Licensees must comply with the following notification requirements [20 CSR 2220-6.050(8)]:

	Timeframe	Notification Requirements	Notification Method
Authorizing Protocol Physician	Within 72 hours after administration	• The identity of the patient • The vaccine(s) administered • The route of administration • The anatomic site of administration • The dose administered • The date of administration	In the pharmacist's discretion, however, documentation of the notification must be maintained.
Primary Care Provider *(If different from the authorizing physician)*	Within fourteen (14) days of administration. * Notification dates should be documented in the patient's record.	Same notification as authorizing physician	Must be in writing. May be transmitted electronically or by fax/ mail. Documentation of notification required.
Adverse Events	Within twenty-four (24) hours after learning of the adverse event/reaction	The authorizing physician must be notified and the patient's primary care provider, if different. Notification must include a description of the adverse event/reaction and any other requirements mandated by protocol.	In the pharmacist's discretion, however, documentation of the notification must be maintained.
State/Federal Entities	As required by law	As required by law	As required by law

A good faith attempt should be made to collect PCP information (i.e., verbally or on the immunization authorization form). PCP notification is only required if the PCP's information is known. The Board suggests documenting if the patient refuses or cannot provide PCP information.

I.6 RECORDS [20 CSR 2220-6.050(7)]

Pharmacists administering vaccines by protocol must document and maintain a record of:

1. *The name, address, and date of birth of the patient;*
2. *The date, route, and anatomic site of the administration;*
3. *The name, dose, manufacturer, lot number, and expiration date of the vaccine;*
4. *The name and address of the patient's primary health care provider, as identified by the patient;*
5. *The name or identifiable initials of the administering pharmacist; and*
6. *Any adverse reaction and who was notified, if applicable.*

Vaccination records must be maintained for at least two (2) years. If vaccines are administered on behalf of a pharmacy, records must be maintained at the pharmacy. If the vaccine is not being administered on behalf of a pharmacy, records should be maintained at an address identified in the protocol.

For additional immunization compliance information, see the Board's Immunization Checklist on the Board's website at http://pr.mo.gov/boards/pharmacy/13863[1].pdf .

J.1 AUTHORIZED ACTIVITY

Pharmacists may administer medications or vaccines pursuant to a medical prescription order subject to the requirements below. [20 CSR 2220-6.040]. Except as provided for intern pharmacists, medication administration may not be delegated.

	Administration Requirements
Qualification Requirements	• Notification of Intent filed with Board (Notifications must be filed online) • Active Missouri RPh license • Current CPR certification from the American Heart Association, American Red Cross or an equivalent body • Completion of drug administration certificate program accredited by ACPE or an entity approved by the Board • A written policy and procedure manual covering all aspects of drug administration, including the disposal of used/contaminated supplies and handling of acute adverse events. Manuals must be annually reviewed and available for inspection.
Notification Renewal	• Notification of Intent filed annually with the Board (Notifications must be filed online) • Current CPR certification • Two (2) CE hours (0.2 CEU) related to drug administration within the prior twelve (12) months
Additional Compliance Requirements	Pharmacists must comply with: • Applicable Centers for Disease Control (CDC) guidelines. • All state and federal laws governing patient information statements and informed consent
Missouri Licensed Intern Pharmacist	• May administer if the intern: • Has a current and active CPR certification • Completed an administration certificate program accredited by ACPE or an entity approved by the Board • Interns must be under the direct supervision of a pharmacist qualified to administer drugs
Authorized Medication/Vaccines	As prescribed

See section E.22 for dispensing naloxone by protocol.

J.2 PRESCRIPTION REQUIREMENTS

To administer medication, the prescription must contain:

1) The prescriber's name;
2) The patient's name;
3) The name of the drug and dose to be administered;

4) The route of administration;
5) The date of the original order;
6) The date or schedule, if any, of each subsequent administration; and
7) A statement that the drug is to be administered by a pharmacist. [20 CSR 2220-6.040(4)]

To be valid for administration, the prescription must include the prescribed route of administration and indicate that the drug is to be administered by a pharmacist. Board inspectors routinely observe non-compliance in this area. A pharmacy may contact the prescriber to get authorization to add these items. Authorization must be documented in the pharmacy's records.

J.3 RECORDS

The following records must be maintained for each administration:

1) The patient's name, address, and date of birth;
2) The date, route, and anatomic site of administration;
3) The name, dose, manufacturer, lot number, and expiration date of the drug;
4) The name and address of the patient's primary health care provider, as identified by the patient;
5) The name or identifiable initials of the administering pharmacist; and
6) The nature of any adverse reaction and who was notified, if applicable. [20 CSR 2220-6.040(6)]

Records must be maintained separately from the pharmacy's prescription records for a minimum of two (2) years.

J.4 REPORTING/NOTIFICATIONS [20 CSR 2220-6.040(7)]

Administration by Prescription Order Notification Requirements

	Timeframe	Notification Requirements	Notification Method
Prescriber	Within 72 hours after administration	• The identity of the patient • The name of the drug administered • The route of administration • The anatomic site of administration • The dose administered • The date of administration	Notification must be documented in the pharmacy's records
Primary Care Provider *(If different from the authorizing physician)*	Within fourteen (14) days of administration	Same notification as authorizing physician	Must be in writing. May be transmitted electronically or by fax/ mail. Documentation of notification required.

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Adverse Events	Within twenty-four (24) hours after learning of the adverse event/ reaction	The prescriber must be notified	Notification must be documented in the pharmacy's records
State/Federal Entities	As required by law	As required by law	As required by law

K.1 GENERAL REQUIREMENTS

Pursuant to § 338.010, a Missouri licensed pharmacist may perform "medication therapy services" after obtaining a certificate of medication therapeutic plan authority from the Board. "Medication therapy services" are defined in 20 CSR 2220-6.060(1)(F) as:

> *[T]he designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol.*

Medication therapy services ("MTS") are different from "medication therapy management." As commonly defined, medication therapy management includes a group of pharmacist provided services designed to optimize patient therapeutic outcomes. Medication therapy management is within the scope of the practice of pharmacy and can be performed by any Missouri licensed pharmacist (i.e., Medicare Part D medication therapy management). A MTS certificate is only required if a pharmacist is engaged in or has authority to initiate or modify drug/device therapy *(i.e., Coumadin/Vancomycin dosing)*.

Modification of drug therapy includes, but is not limited to:

- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different or additional strength, dose, dosage form or dosage schedule; or
- Selecting, adding or changing a new or different route of administration.

Modification does not include dispensing a drug/device pursuant to a valid prescription from an authorized prescriber or selecting a generic substitution as authorized by § 338.056. Additionally, "medication therapy services" do not include administering medication by prescription order pursuant to 20 CSR 2220-6.040 or administering vaccines by protocol pursuant to 20 CSR 2220-6.050.

Prior to performing MT services, a pharmacist must have:

- A MTS certificate issued by the Board, and;
- A protocol with a Missouri licensed physician who is actively practicing medicine in Missouri. (See K.4- Protocol Requirements below).

All pharmacists performing MT services in Missouri are required to have a MTS certificate issued by the Board, including, pharmacists practicing in a hospital. For detailed information on obtaining a MTS certificate, see 20 CSR 2220-6.070 and the Board's Medication Therapy Services Q&A.

K.2 SCOPE OF AUTHORITY

Licensees holding a current MTS certificate may perform medication therapy services as authorized by their governing protocol. However, the following restrictions/prohibitions apply:

- Pharmacists may not initiate or modify any controlled substance.
- Pharmacists may not independently prescribe. Instead, medication may only be modified or initiated as authorized by a written protocol with a Missouri physician.
- MT services may not be delegated. Pharmacy technicians and intern pharmacists may assist in providing MT services under the supervision of a pharmacist. However, technicians and interns may not initiate or modify drug therapy or perform any act that requires the professional judgment of a pharmacist.

K.3 CONTINUING EDUCATION

MTS certificate holders are required to complete 6 hours of CE in courses/programs related to medication therapy management each pharmacist biennial renewal period. The required CE may be used to satisfy Missouri's biennial pharmacist CE requirements.

K.4 PROTOCOL REQUIREMENTS

Prior to performing MT services, pharmacists must have a written protocol with a Missouri licensed physician who is actively practicing medicine in the state of Missouri and whose practice location is no more than fifty (50) miles by road from the pharmacist.

The Board does not have a form or recommended protocol. However, protocols should clearly delineate the pharmacist's scope of authority. As detailed in 20 CSR 2220-6.080(4), protocols must include:

- The names and signatures of the participating physician(s) and pharmacists(s);
- The effective date of the protocol;
- A description of MT services the pharmacist is authorized to provide. Authorized MT services must be within the skill, education, training and competence of the authorizing physician and pharmacist;
- A list of clinical conditions, diagnoses and diseases included in the written protocol and the type of medication therapy allowed in each case;
- The specific drugs or drug categories included in the protocol;
- A statement of the methods, procedures, decision criteria and plan the pharmacist is to follow when providing MT services;
- A description of any authority granted to the pharmacist to administer medication;
- A list of drugs the pharmacist is authorized to administer;
- A description of drug therapy related patient assessment procedures or testing the pharmacist may order or perform;
- Procedures for documenting the pharmacist's MT decisions;
- Procedures and requirements for communicating and reporting MT decisions to the authorizing physician;
- Criteria for timely communication between the pharmacist and authorizing physician;
- A statement prohibiting the pharmacist from delegating the responsibility of MT services;
- Methods for physician review of MT activities;
- Provisions allowing the authorizing physician to access patient records;
- Mechanisms and procedures that allow the authorizing physician to override, rescind or otherwise modify the protocol;
- Emergency response procedures the pharmacist is authorized to follow to address emergency situations, including, anaphylactic or other adverse medication reactions, adverse needle sticks or other adverse events;
- All notification requirements required by 20 CSR 2220-6.080(5) (see K.8); and
- An address where required records will be maintained.

Protocols must be signed and dated by both the authorizing physician and pharmacist. If a protocol includes multiple physicians and pharmacists, a separate protocol is not required for each participating physician/pharmacist if all authorizing physicians and pharmacists sign and date a statement agreeing to be governed by the terms of the protocol.

Alternatively, MT services may be provided pursuant to a protocol approved by the "medical staff committee" of a hospital or hospital system. A "medical staff committee" is defined as the "committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management" (i.e., Pharmacy & Therapeutics Committee). Protocols approved by a medical staff committee can only be used to provide MT services to "individuals receiving medical diagnosis, treatment, or care at a hospital or a hospital clinic or facility." A physician protocol is required for all other services.

Modifications/amendments to the protocol must be documented in writing and signed and dated by both the pharmacist and the authorizing physician prior to being implemented. Protocols may be rescinded by the authorizing physician or pharmacist with or without cause, provided the rescission is documented in writing.

Protocols must be reviewed and signed annually by the authorizing physician and pharmacist. The annual review date must be documented on the written protocol.

Protocols do not have to be filed with the Board but must be available if requested. Additionally, both the pharmacist and authorizing physician must retain signed copies of the written protocol for 8 years after the protocol is terminated.

K.5 PHARMACY RESIDENTS

In lieu of an individual protocol, a pharmacy resident may perform MT services under the written protocol of another Missouri pharmacist if:

- The resident holds a MT certificate from the Board;
- The resident is enrolled in a residency training accredited by the American Society of Health System Pharmacists (ASHP) or that has a valid ASHP accreditation application pending, and;
- The resident is providing MT services under the supervision of a Missouri pharmacist with a current Board MT certificate.

K.6 PRESCRIPTION ORDERS

To provide MT services, a pharmacist must obtain a prescription order from their protocol physician authorizing the pharmacist to perform MT services for a specific patient. Pursuant to 20 CSR 2220-6.080(2)(A), the prescription order must include:

- The patient's name, address and date of birth;
- The date the prescription order was issued;
- The clinical indication for MT services (i.e., the patient's diagnosis or disease);
- The authorizing physician's name and address; and
- The length of time for providing MT services, if less than one (1) year.

Prescription orders for MT services must be in 2-line format as required by § 338.056 and must be maintained in the patient's record (see K.7 below). Prescription orders maintained in compliance with 20 CSR 2220-6.080(2) will be deemed to comply with the general prescription requirements of 20 CSR 2220-2.018.

Prescription orders for MT services are valid for no more than one (1) year and may be transmitted verbally, electronically or in writing.

K.7 DOCUMENTATION OF SERVICES

Pharmacists must document and maintain an adequate patient record of MT services provided for each patient. At a minimum, the patient record must include:

- The patient's name, birthdate, address and telephone number;
- The dates of any patient visits/consultations and the reason for the visit/consultation;
- Any pertinent assessments, observations or findings;

- Any diagnostic testing recommended or performed;
- The name of any medication or device modified;
- The strength, dose, dosage schedule or route of administration of any medication modified or administered;
- Referrals to the authorizing physician;
- Referrals for emergency care;
- Any contact with the authorizing physician concerning the patient's treatment or MT services plan;
- Any informed consent for procedures, medications or devices;
- Any changes/alterations made to the prescription order based on contact with the prescriber; and
- Any consultation with other treatment providers for the patient and the results of the consultation.

K.8 THERAPY MODIFICATIONS

Pharmacists with a MTS certificate may modify drug therapy or device usage as provided in the governing protocol. Pharmacists may only modify non-controlled medications; controlled substances may not be modified by a pharmacist. [20 CSR 2220-6.080(6)(B)]. If the modification results in a drug/device being dispensed, the modification must be documented by creating a prescription in the pharmacy's prescription records under the name of the authorizing physician. [20 CSR 2220-6.080(6)(A)]. All therapy modifications must be documented in the patient's record.

Prescriptions generated by a pharmacist pursuant to 20 CSR 2220-6.080(6)(A) may be dispensed by any licensed pharmacy. However, pharmacists may not sign their name or the physician's name to a written prescription generated under 20 CSR 2220-6.080(6). Instead, modifications may be verbally submitted to the other pharmacy or e-prescribed in accordance with governing law and the governing protocol under the protocol physician's name.

K.9 NOTIFICATIONS

Rule 20 CSR 2220-6.080(5) requires the following notifications:

TYPE	RECIPIENT	TIMEFRAME
Anaphylactic or adverse medication reactions, adverse needle sticks or other adverse events	Authorizing physician or physician's authorized designee	24 Hours
Therapy modifications	Authorizing physician or physician's authorized designee	24 Hours
Other notifications	As governed by protocol	As governed by protocol

Notifications must be in writing unless otherwise authorized by protocol. Pharmacists providing MT services for, or on behalf of, a health care entity may satisfy the notification requirements if the notification is recorded in a patient medical record that the health care entity is required to maintain under state or federal law (e.g., an EMR). Protocols may include more stringent notification requirements.

K.10 RECORDS

The following records must be maintained under 20 CSR 2220-6.080:

TYPE	TIMEFRAME
Patient records required by 20 CSR 2220-6.080(7)	7 years after termination of protocol
Protocols, including, protocol changes or amendments	8 years after termination of protocol
Prescription orders for MT services	7 years after termination of protocol
Other records required by protocol	As governed by protocol

Records may be electronically maintained provided the record can be retrieved/reviewed on request. Records maintained at a pharmacy must be produced during an inspection or investigation. Records not maintained at a pharmacy must be produced within three (3) business days.

L.1 REGISTRATION REQUIREMENTS

All pharmacy technicians must be registered with the Board. [§ 338.013, 20 CSR 2220-2.700]. A pharmacy technician is defined as any person who assumes a supportive role or who is utilized to "perform routine functions. . .in connection with the receiving, preparing, compounding, distributing or dispensing of medication." [20 CSR 2220-2.700]. Additionally, "any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis" must be registered as a technician.

To be registered, an applicant must submit an application with the applicable fee and undergo a criminal history background check. Missouri does not currently impose minimum education or certification requirements for technician registration. However, technicians should be appropriately trained to perform the tasks delegated. *Note: Additional training is required for sterile compounding. [20 CSR 2220-2.200(3)].*

Applicants may begin working as a pharmacy technician once a completed registration application has been mailed to the Board. To be complete, the application must include an official fingerprint receipt and the required fee. A copy of the application must be maintained at the pharmacy. [§ 338.013]. The Board also recommends maintaining proof of mailing.

Pharmacies must maintain a current list of all pharmacy technicians authorized to access the pharmacy and their duties, as well as a policy and procedure manual for technician supervision. [20 CSR 2220-2.090(2)(BB), (CC)].

Prescription delivery staff that solely perform delivery functions do not have to be registered as technicians. However, technician registration may be required if additional functions are performed.

The pharmacist-in-charge is responsible for determining if an individual has "independent access" to drug stock. The Board has determined that the ability to access the pharmacy does not automatically require technician registration (i.e., an employee/auditor has a key to the pharmacy). However, individuals who use their access to independently enter the pharmacy must be registered.

L.2 SUPERVISION/ALLOWED ACTIVITIES

A pharmacy technician may assist in any area of pharmacy practice, including, receiving, preparing, compounding or dispensing prescriptions. [20 CSR 2220-2.700(1)]. However, technicians may not work independently and must be under the "direct supervision and responsibility" of a Missouri-licensed pharmacist at all times. [20 CSR 2220-2.700]. All prescriptions prepared or compounded by a technician must be finally verified/checked by a pharmacist, including, reconstituted products.

Technicians may not perform any activity that requires the "professional judgment" of a pharmacist. [20 CSR 2220-2.700(1)]. Prohibited activities include, but are not limited to,:

- Final verification of a prescription before dispensing;
- Receiving or providing refill transfer information for controlled substance prescriptions [20 CSR 2220-2.120(1)(D)];
- Drug utilization review; and
- Patient counseling.

The Board has determined that technicians may accept written prescriptions from patients for dispensing when no pharmacist is on duty. [20 CSR 2220-2.010(1)(B)]. However, technicians cannot take verbal prescription orders or count, fill, compound or enter a prescription if the pharmacist is absent. Technicians cannot come in early to process prescriptions before a pharmacist arrives or hand out or dispense prescriptions when no pharmacist is on duty, even if the prescription was previously checked by a pharmacist.

L.3 RENEWALS

Technician registrations are valid for one (1) year and expire annually on May 31st. A technician may not work if his/her registration is not renewed by May 31st. [§ 338.013.5]. Technicians who fail to renew by May 31st may submit a late renewal application until June 30th. Although the Board will accept the renewal application, the individual cannot work after May 31st until his/her registration has been renewed by the Board. Applicants wishing to renew after June 30th will be required to submit a new technician registration application and undergo a new criminal history background check.

Registration status may be checked on the Board's website at https://renew.pr.mo.gov/pharmacy-licensee-search.asp. Practicing without a valid registration and/or allowing unlicensed practice constitutes grounds for discipline. [§ 338.055.2(10)].

L.4 MANDATORY REPORTING OF TECHNICIAN DISCIPLINE [§ 338.013.10]

Hospitals and licensed pharmacies are required to report to the Board any final disciplinary action taken against a technician for conduct that may constitute grounds for discipline under § 338.055. This requirement applies to any form of final disciplinary action, including, but not limited to, probation, suspension, demotion or reassignment. Pharmacies must also report any technician who voluntary resigns if a complaint or report has been made against the technician which could have led to final disciplinary action and the actions alleged in the complaint/report are cause for discipline under § 338.055. *(See C-15 for examples of causes to discipline under § 338.055.)*

Written notice of technician action must be filed with the Board in writing within fifteen (15) days after the action. [20 CSR 2220-2.010(1)(P)]. Notifications must include:

- The name and permit number of the pharmacy;
- The name of the person making the notification;
- The technician's name and registration number;
- Date of action; and
- Reason for action.

Notification of Technician Action notices may be electronically filed on the Board's website.

L.5 DISCIPLINED/DISQUALIFIED TECHNICIANS`

Section 338.013.2, RSMo, authorizes the Board to place a technician on the Employment Disqualification List ("EDL") if cause exists for disciplining the technician under § 338.055.2, RSMo. Technicians on the Employment Disqualification List are not authorized to work and should be immediately removed from the pharmacy.

Alternatively, the Board may place a technician on discipline by issuing a conditional registration. Technicians with a conditional registration are eligible to work subject to the conditions printed on the back of his/her registration.

To assist employers, the Board publishes an online Employment Disqualification List (EDL) and a separate Conditional

Registration list. The lists are available at:

- Employment Disqualification List: http://pr.mo.gov/boards/pharmacy/disqlist.pdf
- Conditional Registration List: http://pr.mo.gov/boards/pharmacy/Conditional%20list.pdf

These lists are updated frequently. The Board sends free electronic alerts (e-alerts) when individuals are added to either list. Interested parties may sign up for the Board's e-alerts at http://pr.mo.gov/pharmacists-newsletter.asp.

Licensees are responsible for ensuring technicians are appropriately authorized to work. The Board recommends designating a specific person and setting regular intervals for checking the EDL and the Conditional Registration lists.

OTHER TECHNICIAN EXCLUSIONS

Pharmacists, technicians and interns may be prohibited or restricted from working under other state/federal laws. Licensees should conduct thorough background checks to ensure compliance:

HB 600: The Missouri Department of Revenue may suspend a licensee/registrant by operation of law if the licensee/registrant has failed to file a tax return or is delinquent on state taxes. INDIVIDUALS ON THE HB 600 LIST ARE NOT AUTHORIZED TO WORK. The HB 600 list is regularly updated and is available online at http://pr.mo.gov/boards/pharmacy/HB600List.pdf. Updates to the HB 600 list are also included in the Board's e-alerts.

WAIVERS: Both state and federal law prohibit an employer from employing individuals with certain controlled substance related convictions without an employment waiver. Specifically, a DEA waiver is required for felony controlled substance related convictions. A Missouri BNDD waiver is required for both misdemeanor and felony controlled substance related convictions. Waivers may be required even if the Board has issued a license/registration.

Licensees should conduct thorough background checks to ensure compliance. The Board is legally prohibited from sharing confidential criminal history information. Questions about controlled substance waivers should be addressed to BNDD or the DEA.

DHHS-OIG Exclusion List: The OIG Exclusion List includes entities/persons excluded from participating in Medicare, Medicaid and other federal health care programs. Employers participating in qualified federal programs are generally prohibited from employing individuals on the OIG list. For additional information, visit OIG's website at: http://oig.hhs.gov/exclusions/index.asp.

****These exclusions/waivers also apply to pharmacists and interns****

L.6 TECHNICIAN COMPLIANCE RESOURCES

The Board has published a Pharmacy Technician Guide that includes specific compliance information for Missouri technicians. The Board has also published an online Technician Quiz that can be used to test your knowledge of Missouri's technician requirements. The free online quiz can be taken anonymously and can help assess your understanding of Missouri law.

M.1 LICENSE REQUIREMENTS

A Missouri Class C Long-Term Care pharmacy permit is required if a pharmacy provides prescription services to a long-term care ("LTC") facility or dispenses legend drugs/devices to patients residing in a LTC facility. [20 CSR 2220-2.140]. A Class C permit is required regardless of the number of patients served (i.e., one patient or the entire long-term care facility). As used in the Board's rules, a "long-term care facility" is defined as a "nursing home, retirement care, mental care or other facility or institution that provides extended health care to resident patients." [20 CSR 2220-2.020(9)(C)].

Pursuant to 20 CSR 2220-2.140(2), Class C pharmacies must have a policy and procedure manual that includes:

- Methods for timely dispensing medication;
- Procedures for notifying the facility when a medication is not readily available;
- Labeling requirements and policies;
- Policies/procedures for appropriate medication destruction and/or returning unused medication, as authorized by state and federal law; and
- Policies/procedures for securing, delivering, storing and handling emergency kits.

M.2 AUTHORIZED DISPENSING

Licensees may dispense legend drugs to a LTC resident upon receipt of a prescription or upon receipt of a "*prescription drug order*." For purposes of LTC dispensing, a "*prescription drug order*" is defined as "an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient's medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device." [20 CSR 2220-2.140(5)].

Generic substitution is allowed if authorized by the prescriber. [20 CSR 2220-2.140(5)(B)]. Clear documentation of substitution authorization must be maintained, as required by 20 CSR 2220-2.018(1)(H) and 20 CSR 2220-2.080(2)(M).

Pharmacies may maintain a separate file for LTC prescription drug orders, provided that a separate numbering system is used for prescription drug orders. [20 CSR 2220-2.140(5)(C)]. Pharmacies using interim dispensing systems must have records that clearly record these dispensings as any other new or refill dispensing. A pharmacy using an electronic record keeping system must document interim dispensing in the electronic system and may not use a manual record system to record them.

Under 20 CSR 2220-2.140(5)(D), refills associated with a nursing home order are not valid for transfer or use outside of the facility.

M.3 PREPARATION/PACKAGING

Personnel packaging drugs must wear gloves when handling individual tablets and capsules. Drug containers must meet minimum USP requirements, including, but not limited to, single unit, unit dose and unit-of-use containers. [20 CSR 2220-2.140(2)(C)]. If applicable, light sensitive packaging must be used. Internal liners must always be replaced before refilling the container. If drugs are dispensed in a container other than the manufacturer's original container, the container must bear the manufacturer's expiration date or a twelve (12) month expiration date, whichever is less. [20 CSR 2220-2.140(3)].

The Board is aware of packaging used by long-term care pharmacies that involve plastic liners within a hard plastic container. These liners must be changed on each initial and refill dispensing.

M.4 LABELING

Containers dispensed to LTC facilities must comply with all state and federal labeling requirements. [20 CSR 2220-2.140(5)(D)]. However, Missouri law authorizes the following exceptions for unit-dose containers:

- The drug name/strength, control number, expiration date and manufacturer's name may be included on the package, and;
- The patient's name and directions do not have to appear on the container label if the LTC facility has a mechanism that will identify the medication each patient is to receive, the personnel administering the medication and the directions for administration. [20 CSR 2220-2.140(2)(B)].

A bubble card is not considered a unit-dose container and must bear a full prescription label.

In the event of a change in directions, a pharmacist may change the container label, however, the pharmacist must personally affix the revised label. Revised prescription labels may not be sent to the LTC facility for their staff to apply. [20 CSR 2220-2.140(2)(B)]. All drugs dispensed to a LTC facility must have an expiration date on the container.

M.5 RETURN, RE-USE & DISPOSAL

Licensees may receive non-controlled drugs returned from a long-term care facility, hospital or a hospice facility regulated by the Missouri Department of Health and Senior Services under 19 CSR 30-35.020, if:

1) The medication was originally dispensed by the pharmacist or pharmacy to the institution/facility;
2) The pharmacist has assurance from a person at the institution/facility responsible for the medication that the drugs were stored in accordance with the manufacturer's recommendations and USP standards; and
3) There is an established mechanism to trace the expiration date and the manufacturer's lot number for the returned medication.

Returned drugs from a long-term care facility, hospital or hospice facility may be reused if:

1) The drug products are returned sealed in the original manufacturer's tamper-evident packaging; or
2) The drug products were repackaged by a licensed pharmacy or an FDA-registered repackager and are returned sealed in the repackager's tamper-evident packaging, or;
3) The drug products are returned in unit-of-use packaging and the unused portions can be separated and reused without any further repackaging.

Returned medication from a long-term care/hospice facility or a hospital must be re-labeled to provide accurate patient and prescription information. The original lot numbers, expiration date(s) or beyond-use-date(s) may not be altered.

Controlled substances may not be returned from a LTC facility.

BOARD OF PHARMACY

- Website
- Publications/Resources Page

Publications

- Immunization/Administration Checklist
- Medication Therapy Services Compliance Guide
- Pharmacy Inspection Checklist
- Pharmacy Inspection Guide
- Missouri Pharmacy Practice Guide
- Pharmacy Practice Guide Continuing Education Exam
- Pharmacy Self-Assessment Guide
- Pharmacist-In-Charge FAQ
- Pharmacy Compliance Top 10
- Reconciling Your Inventory
- Technician Compliance Guide

Videos/Webinars

- Available on-demand

MISSOURI BUREAU OF NARCOTICS AND DANGEROUS DRUGS (BNDD)

- BNDD Website
- BNDD Newsletter/Publications
- Controlled Substance Guidelines for Pharmacies
- Mid-Level Practitioner & Controlled Substance Guidelines
- Missouri Changes to Prescriptions Guidelines

DRUG ENFORCEMENT ADMINISTRATION (DEA)

- DEA Website
- Controlled Substances Act
- DEA Rules
- DEA Pharmacist Manual
- DEA Statement on Agents of Prescribers